US009072903B2

(12) **United States Patent**
Kaula et al.

(10) **Patent No.: US 9,072,903 B2**
(45) **Date of Patent: Jul. 7, 2015**

(54) **SYSTEM AND METHOD OF ESTABLISHING A PROTOCOL FOR PROVIDING ELECTRICAL STIMULATION WITH A STIMULATION SYSTEM TO TREAT A PATIENT**

(75) Inventors: **Norbert Kaula**, Arvada, CO (US); **Yohannes Iyassu**, Denver, CO (US); **Richard J. Polefko**, Parma, OH (US); **Steven E. Wilder**, Ashland, OH (US); **Scott G. Leyh**, Cleveland Heights, OH (US)

(73) Assignee: **Greatbatch Ltd.**, Clarence, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 106 days.

(21) Appl. No.: **13/118,775**

(22) Filed: **May 31, 2011**

(65) **Prior Publication Data**

US 2012/0310300 A1 Dec. 6, 2012

(51) **Int. Cl.**

A61N 1/00	(2006.01)
A61N 1/36	(2006.01)
A61N 1/372	(2006.01)
A61N 1/05	(2006.01)
G06F 19/00	(2011.01)

(52) **U.S. Cl.**

CPC ***A61N 1/36125*** (2013.01); *A61N 1/0551* (2013.01); ***A61N 1/36132*** (2013.01); ***A61N 1/37247*** (2013.01); *G06F 19/3412* (2013.01)

(58) **Field of Classification Search**

USPC 607/46, 59, 60

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,978,171	B2	12/2005	Goetz et al.	
7,174,215	B2 *	2/2007	Bradley	607/59
7,263,402	B2 *	8/2007	Thacker et al.	607/46
7,881,805	B2	2/2011	Bradley et al.	
2001/0034542	A1	10/2001	Mann	
2006/0241722	A1	10/2006	Thacker et al.	
2006/0253174	A1 *	11/2006	King	607/62
2006/0293720	A1	12/2006	DiLorenzo	
2007/0032834	A1	2/2007	Gliner et al.	
2007/0167991	A1	7/2007	DiLorenzo	
2007/0255346	A1	11/2007	Rondoni et al.	
2008/0215118	A1 *	9/2008	Goetz et al.	607/59
2009/0018617	A1	1/2009	Skelton et al.	
2009/0118786	A1	5/2009	Meadows et al.	
2009/0234422	A1 *	9/2009	Goetz et al.	607/66
2010/0010584	A1	1/2010	Skelton et al.	
2010/0010585	A1	1/2010	Davis et al.	
2010/0010589	A1	1/2010	Skelton et al.	
2010/0023090	A1	1/2010	Jaax et al.	

(Continued)

OTHER PUBLICATIONS

Freescale Semiconductor, Inc., "i.MX51 Applications Processors for Consumer and Industrial Products," Data Sheet: Technical Data, Document No. IMX510EC, Rev. 4 (Aug. 2010) 200 pages.

(Continued)

Primary Examiner — Niketa Patel

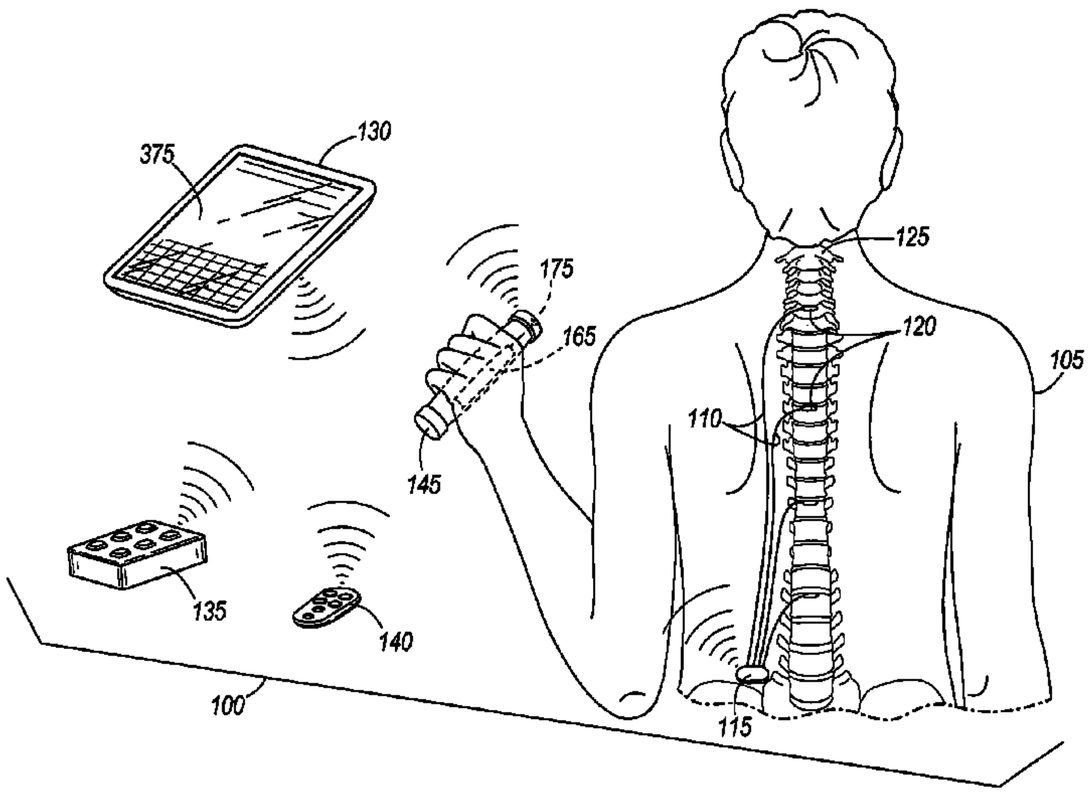
Assistant Examiner — William Levicky

(74) *Attorney, Agent, or Firm* — Michael Best & Friedrich LLP

(57) **ABSTRACT**

A stimulation system, such as a spinal cord stimulation (SCS) system, having a programmer and a patient feedback device for establishing a protocol to treat a patient. The programmer uses a computer assisted stimulation programming procedure for establishing the protocol. Also described are methods of treating a patient with a spinal cord stimulation system including the programmer and the patient feedback device.

21 Claims, 14 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

2010/0121408	A1*	5/2010	Imran et al.	607/46
2010/0268304	A1	10/2010	Matos	
2010/0292556	A1	11/2010	Golden	
2011/0040546	A1	2/2011	Gerber et al.	
2011/0093030	A1*	4/2011	Goetz et al.	607/17
2012/0310299	A1	12/2012	Kaula et al.	

OTHER PUBLICATIONS

North, R.B. et al., "Patient-interactive, computer-controlled neurological stimulation system: clinical efficacy in spinal cord stimulator adjustment," J. Neurosurg. (1992) 76(6):967-972, http://www.ncbi.nlm.nih.gov/pubmed/1588431.

Texas Instruments Inc., "Mixed Signal Microcontroller," brochure, MSP430G2x32, MSP430G2x02; SLAS723 (Dec. 2010) 53 pages.

Virtualmedicalcentre.com, "Spinal Cord Stimulation Devices," http://www.virtualmedicalcentre.com/devices.asp?sid=2 (Nov. 1, 2008) 7 pages.

European Search Report for Application No. 12169540.7 dated Sep. 26, 2012 (8 pages).

European Search Report for Application No. 12169540.7 dated Dec. 10, 2012 (2 pages).

United States Patent Office Action for U.S. Appl. No. 13/118,764 dated Dec. 19, 2012 (19 pages).

United States Patent Office Final Rejection for U.S. Appl. No. 13/118,764 dated Jul. 30, 2013 (36 pages).

United States Patent Office Final Rejection for U.S. Appl. No. 13/118,764 dated Jul. 30, 2014 (21 pages).

* cited by examiner

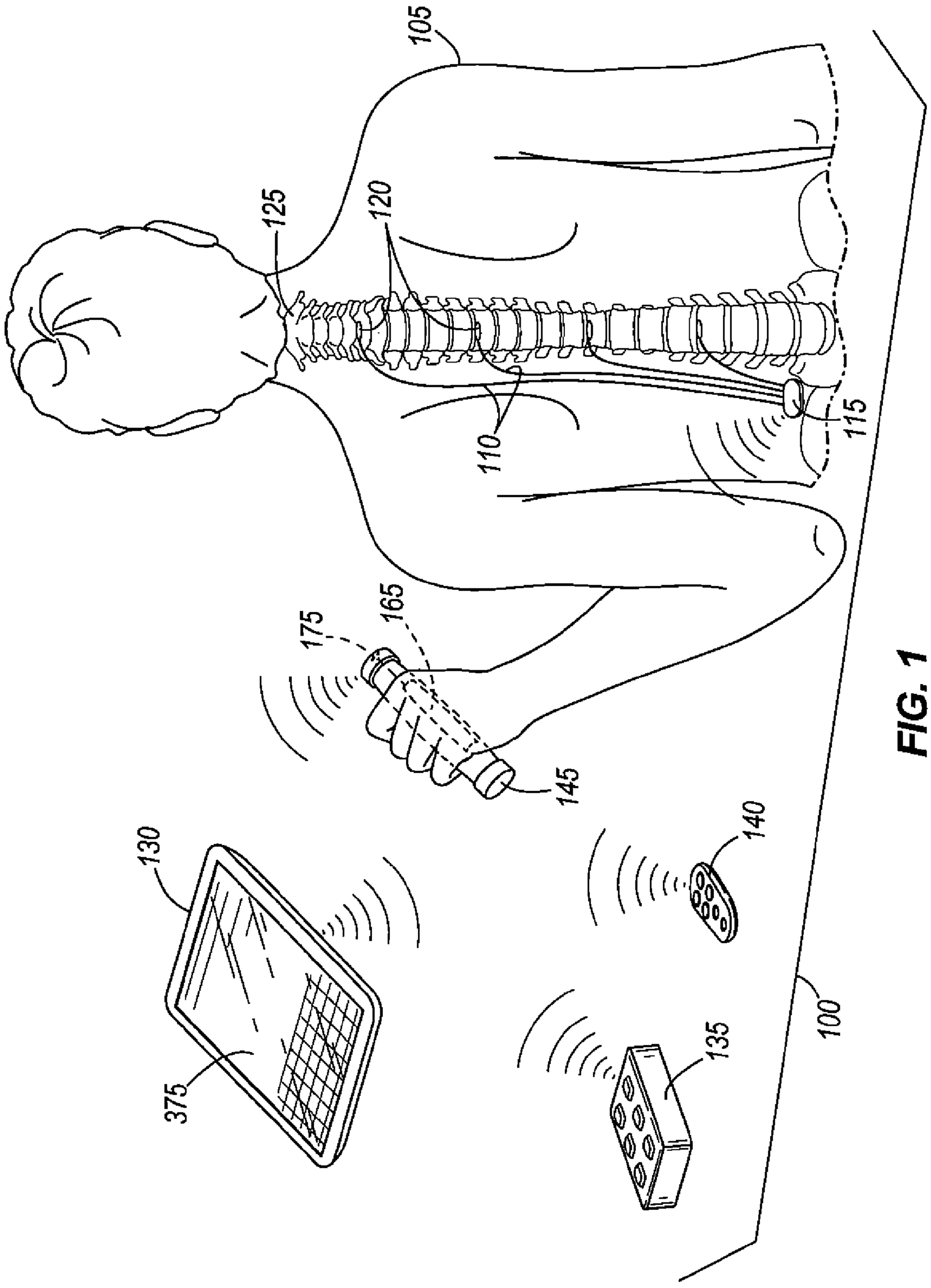


FIG. 1

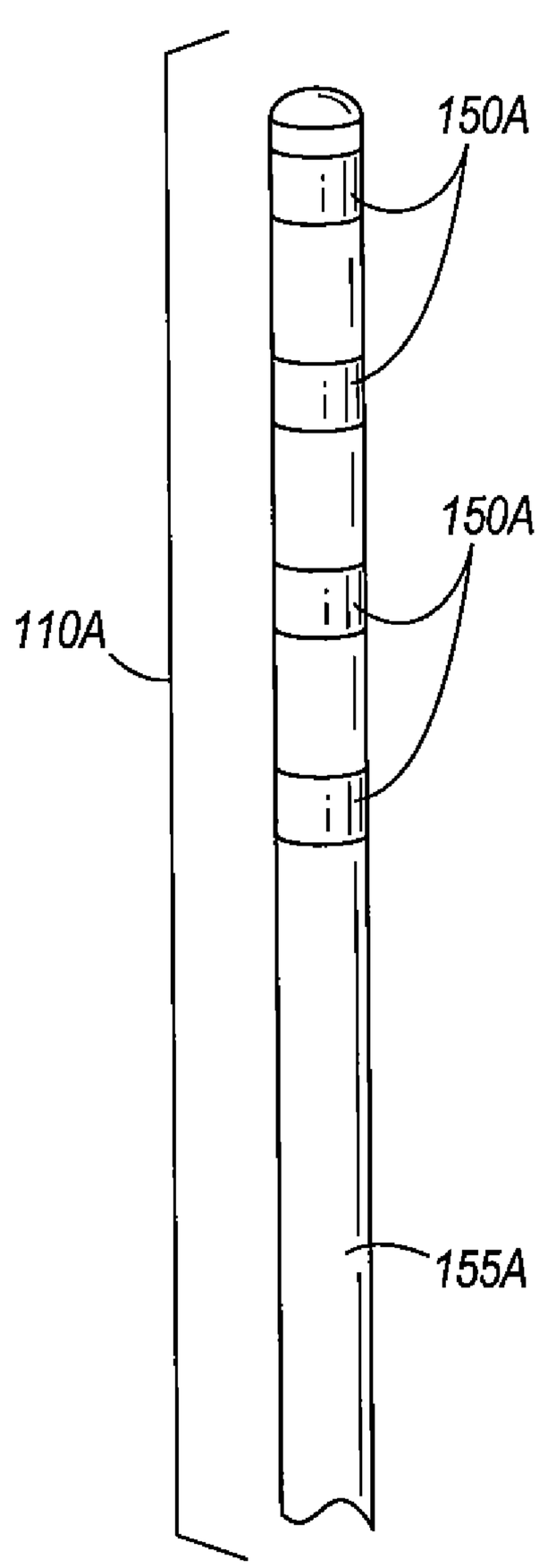


FIG. 2

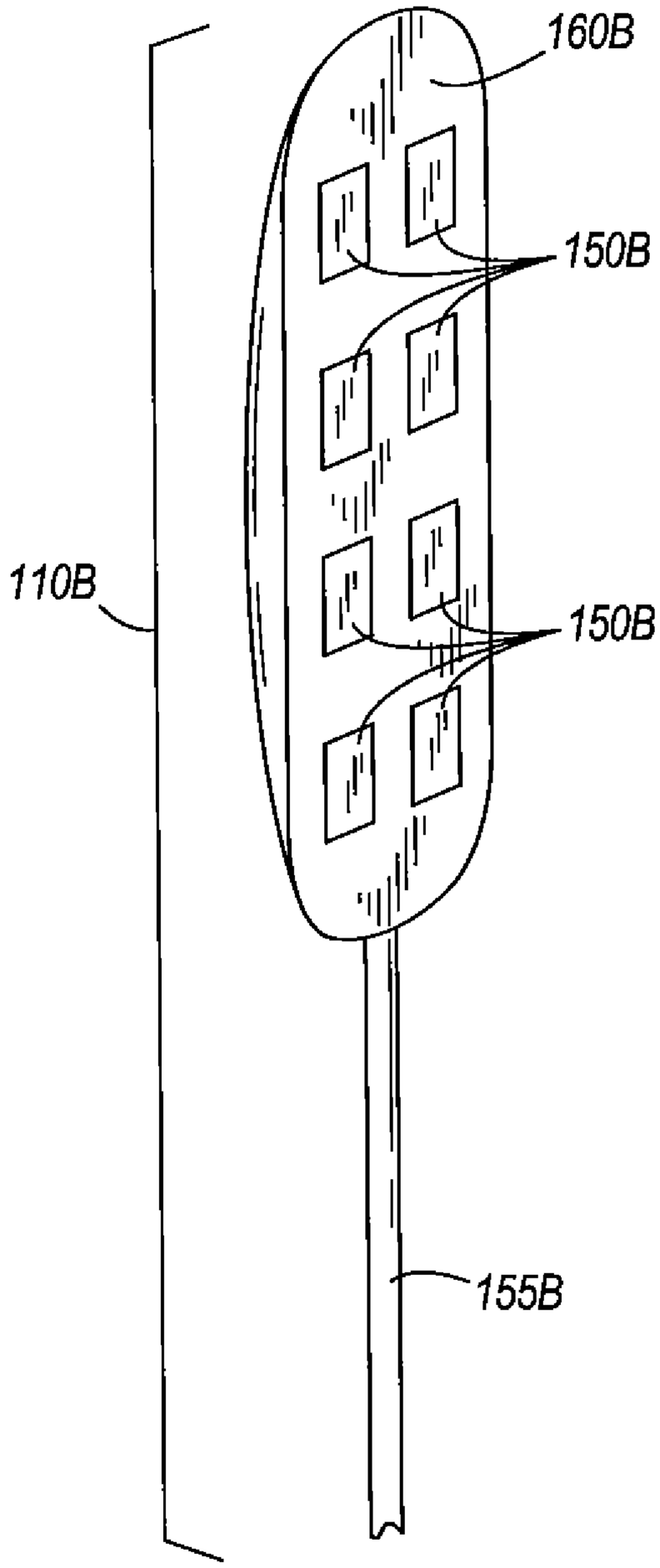


FIG. 3

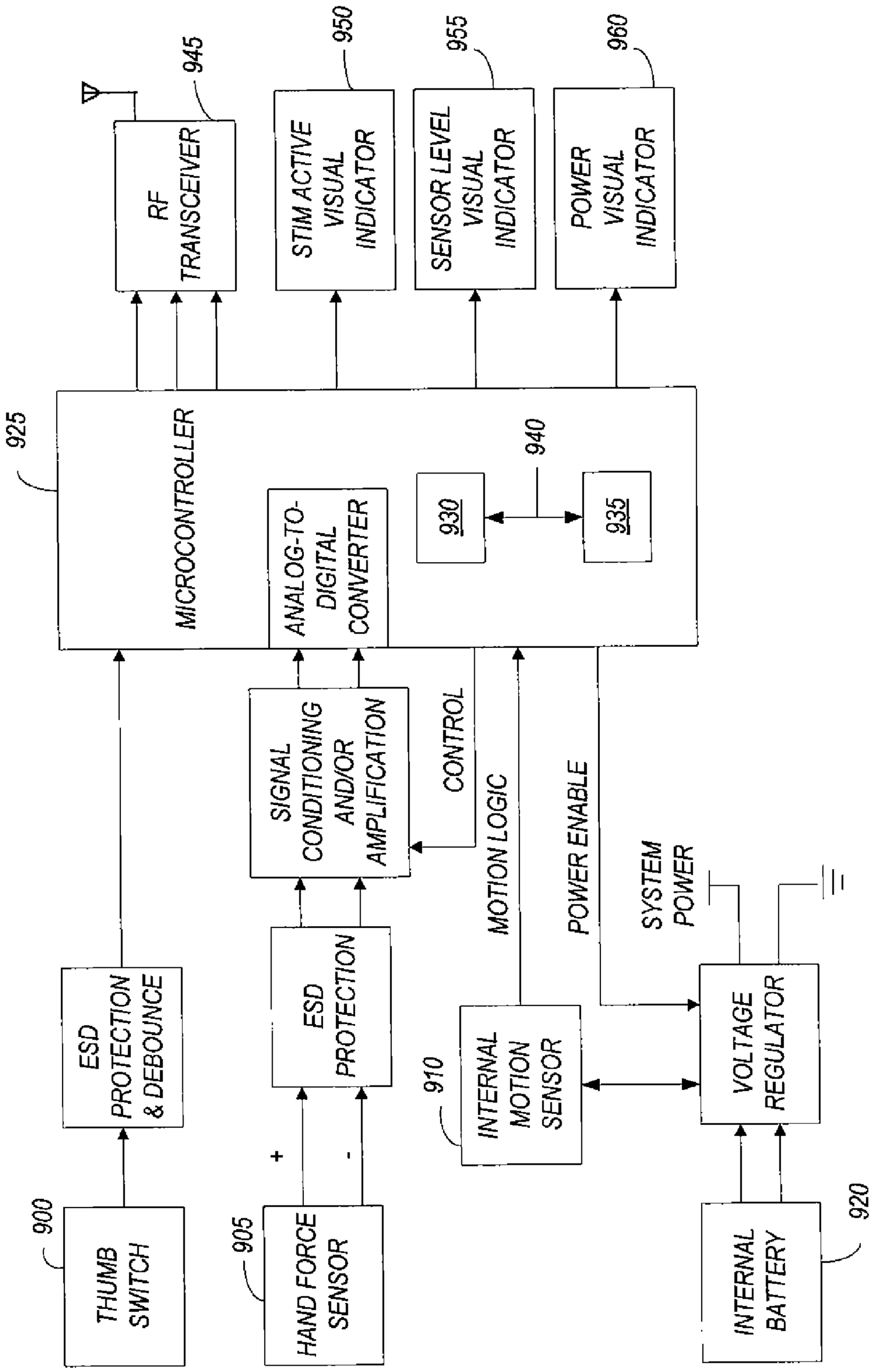

925
MICROCONTROLLER
ANALOG-TO-DIGITAL CONVERTER
930
940
935
945
RF TRANSCEIVER
950
STIM ACTIVE VISUAL INDICATOR
955
SENSOR LEVEL VISUAL INDICATOR
960
POWER VISUAL INDICATOR
SIGNAL CONDITIONING AND/OR AMPLIFICATION
CONTROL
MOTION LOGIC
POWER ENABLE
SYSTEM POWER
ESD PROTECTION & DEBOUNCE
ESD PROTECTION
900
THUMB SWITCH
905
HAND FORCE SENSOR
910
INTERNAL MOTION SENSOR
VOLTAGE REGULATOR
920
INTERNAL BATTERY
+
-

FIG. 4

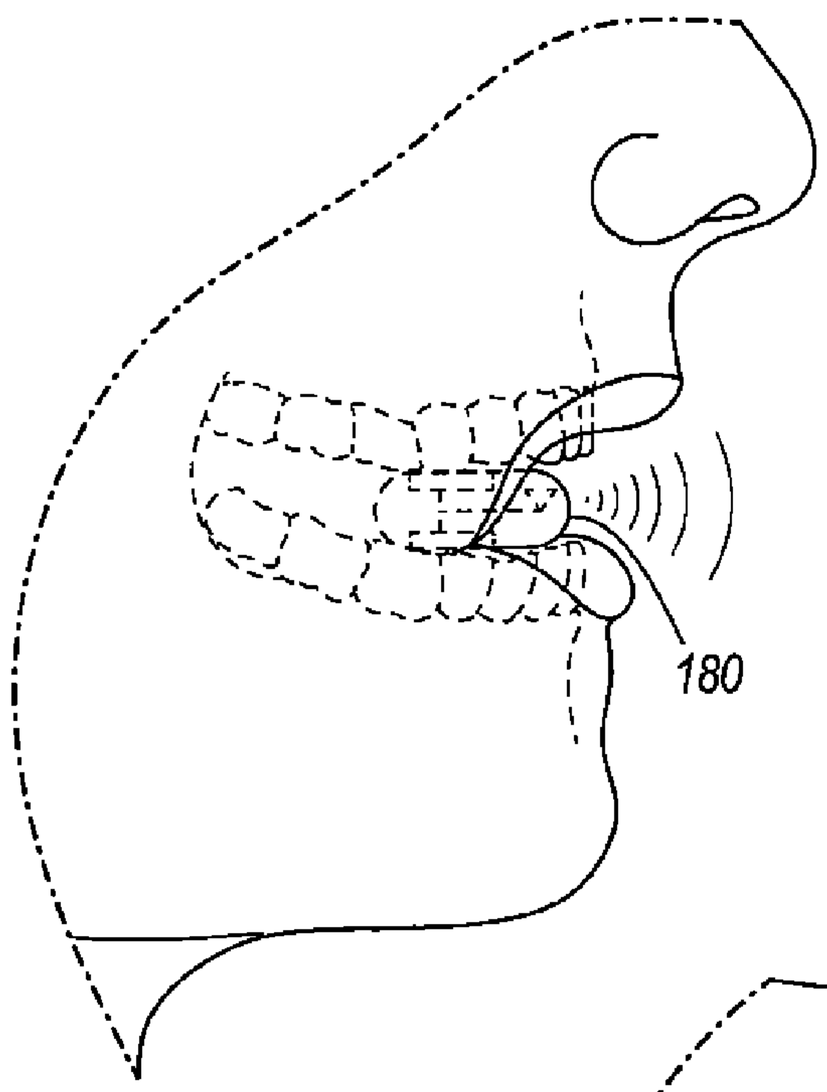


FIG. 5

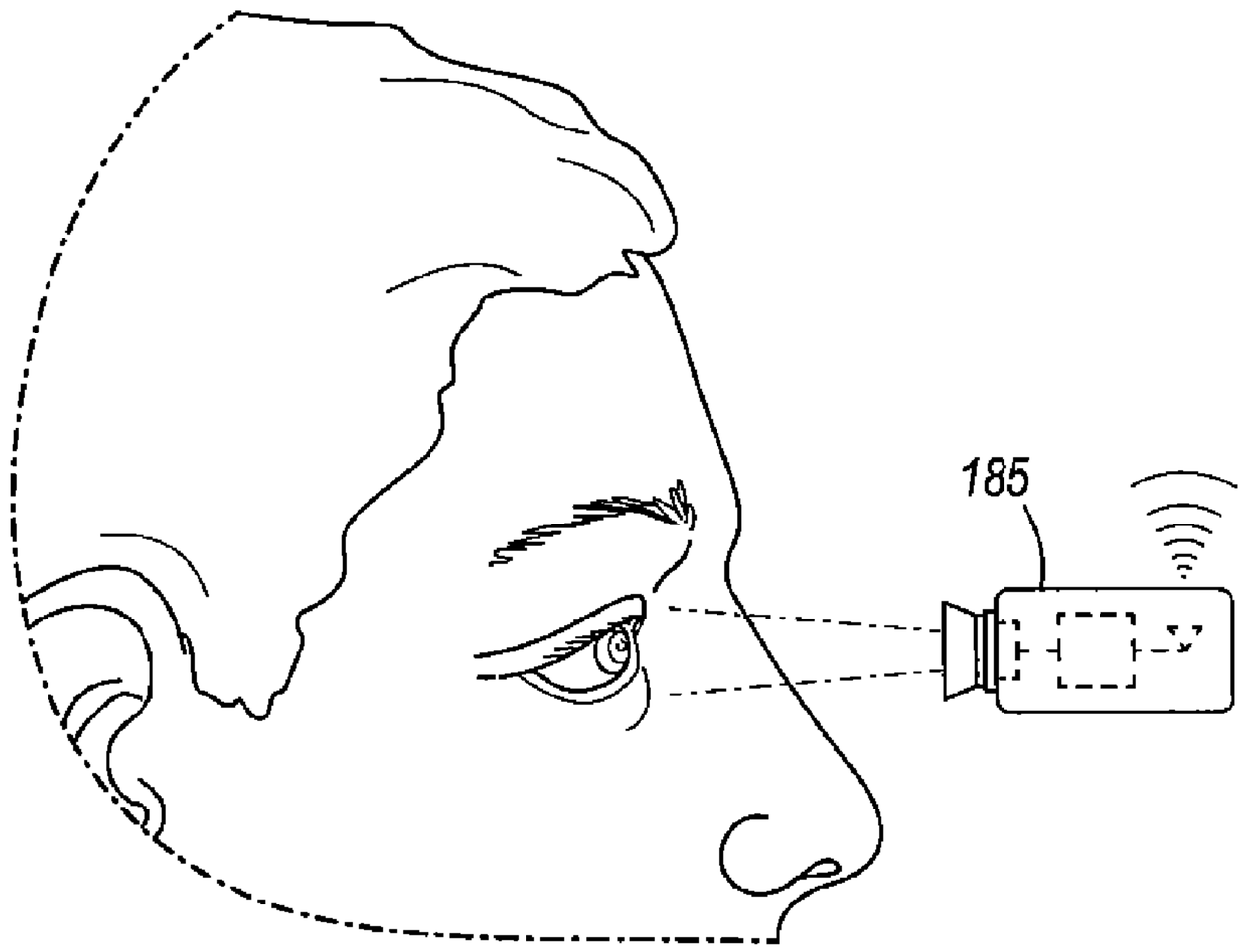


FIG. 6

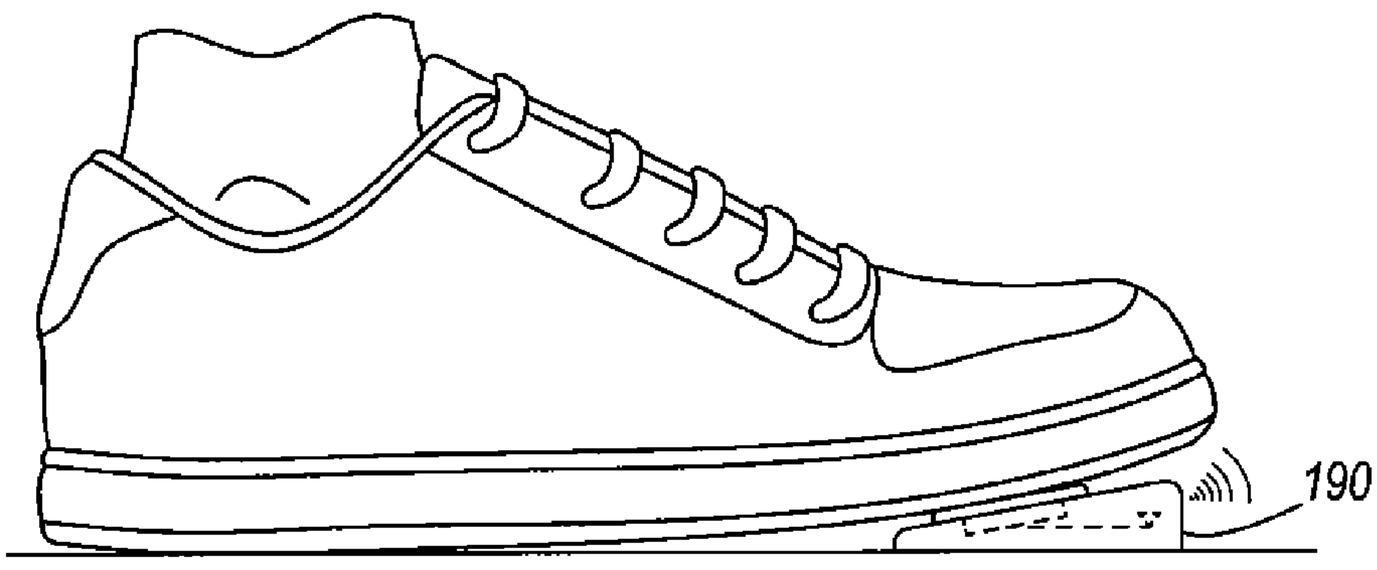


FIG. 7

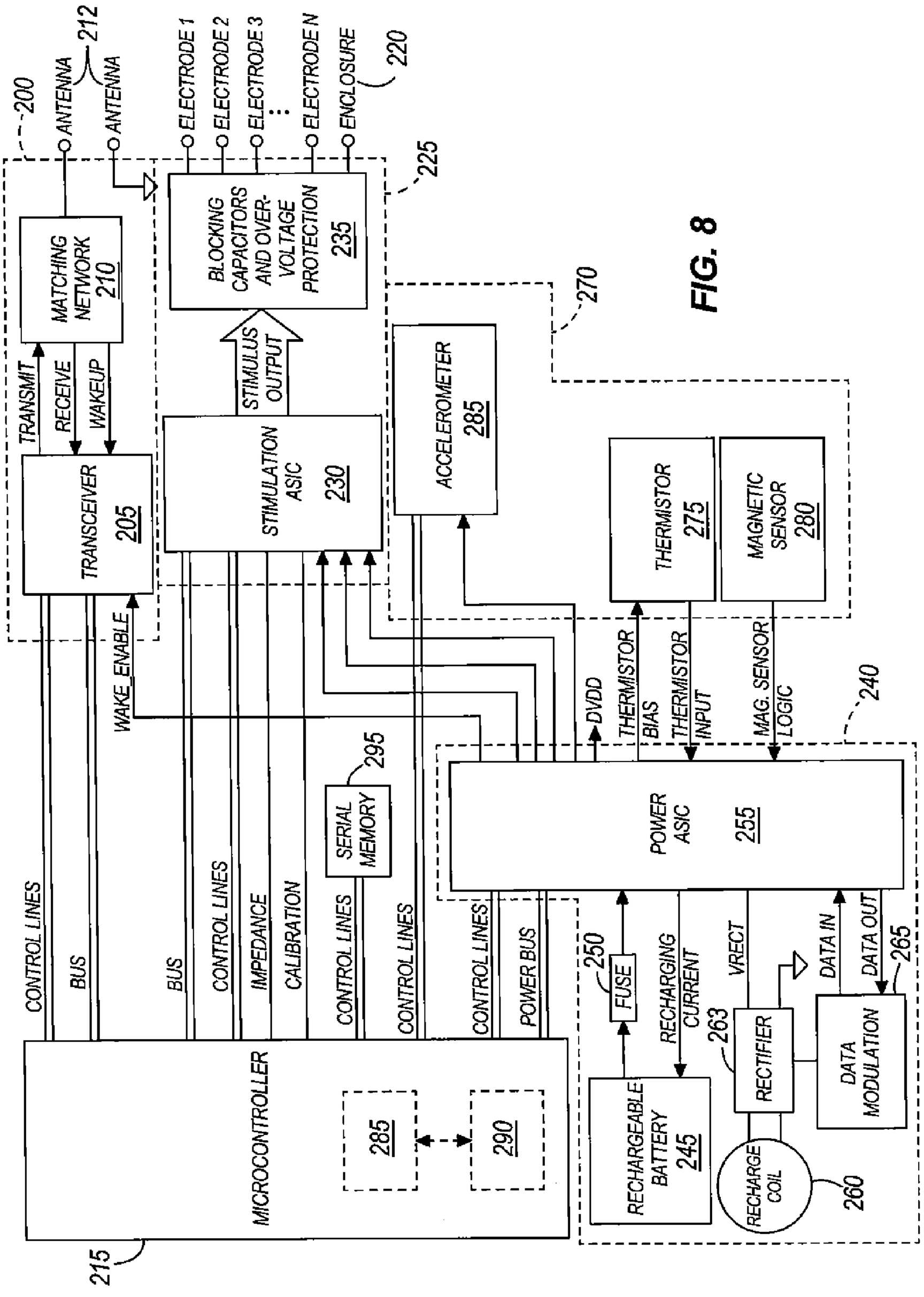

200
ANTENNA
212
ANTENNA
ELECTRODE 1
ELECTRODE 2
ELECTRODE 3
ELECTRODE N
ENCLOSURE
220
225
MATCHING NETWORK 210
BLOCKING CAPACITORS AND OVER-VOLTAGE PROTECTION 235
270
TRANSMIT
RECEIVE
WAKEUP
STIMULUS OUTPUT
TRANSCEIVER 205
STIMULATION ASIC 230
ACCELEROMETER 285
THERMISTOR 275
MAGNETIC SENSOR 280
WAKE_ENABLE
DVDD
THERMISTOR BIAS
THERMISTOR INPUT
MAG. SENSOR LOGIC
240
SERIAL MEMORY
295
POWER ASIC 255
CONTROL LINES
BUS
BUS
CONTROL LINES
IMPEDANCE
CALIBRATION
CONTROL LINES
CONTROL LINES
CONTROL LINES
POWER BUS
250
FUSE
RECHARGING CURRENT
263
VRECT
DATA IN
DATA OUT
265
RECHARGEABLE BATTERY 245
RECTIFIER
DATA MODULATION
RECHARGE COIL
260
MICROCONTROLLER
285
290
215

FIG. 8

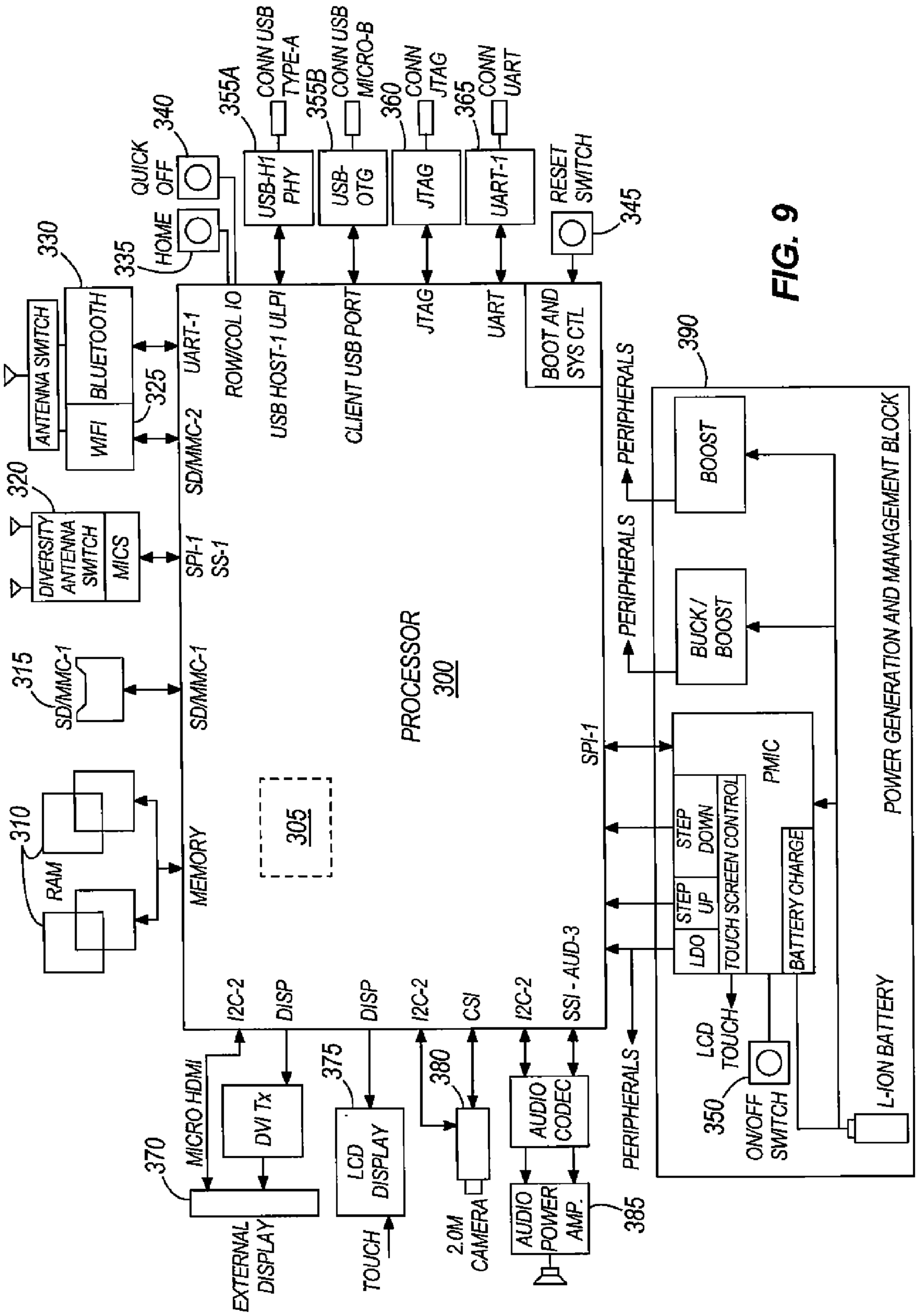

330
335
340
QUICK OFF
HOME
355A
CONN USB TYPE-A
355B
CONN USB MICRO-B
360
CONN JTAG
365
CONN UART
345
RESET SWITCH
USB-H1 PHY
USB-OTG
JTAG
UART-1
ROW/COL IO
USB HOST-1 ULPI
CLIENT USB PORT
JTAG
UART
BOOT AND SYS CTL
ANTENNA SWITCH
BLUETOOTH
WIFI
325
UART-1
SD/MMC-2
320
DIVERSITY ANTENNA SWITCH
MICS
SPI-1
SS-1
315
SD/MMC-1
SD/MMC-1
310
RAM
MEMORY
305
PROCESSOR 300
I2C-2
DISP
DISP
I2C-2
CSI
I2C-2
SSI - AUD-3
SPI-1
PERIPHERALS
PERIPHERALS
390
BOOST
BUCK / BOOST
PMIC
STEP DOWN
STEP UP
LDO
TOUCH SCREEN CONTROL
BATTERY CHARGE
POWER GENERATION AND MANAGEMENT BLOCK
L-ION BATTERY
LCD TOUCH
350
ON/OFF SWITCH
370
MICRO HDMI
DVI Tx
EXTERNAL DISPLAY
375
LCD DISPLAY
TOUCH
380
2.0M CAMERA
AUDIO CODEC
AUDIO POWER AMP.
385

FIG. 9

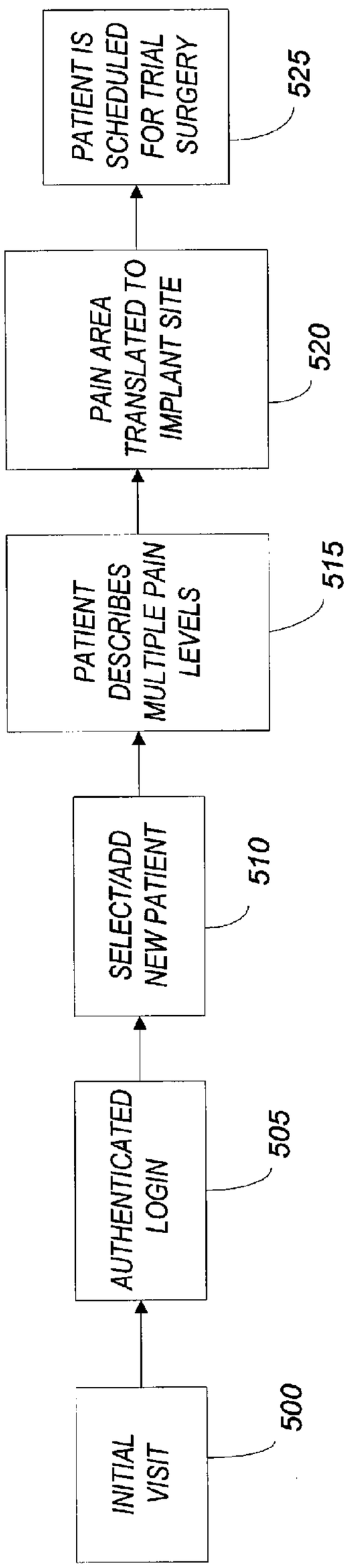

INITIAL VISIT
500
AUTHENTICATED LOGIN
505
SELECT/ADD NEW PATIENT
510
PATIENT DESCRIBES MULTIPLE PAIN LEVELS
515
PAIN AREA TRANSLATED TO IMPLANT SITE
520
PATIENT IS SCHEDULED FOR TRIAL SURGERY
525

FIG. 10

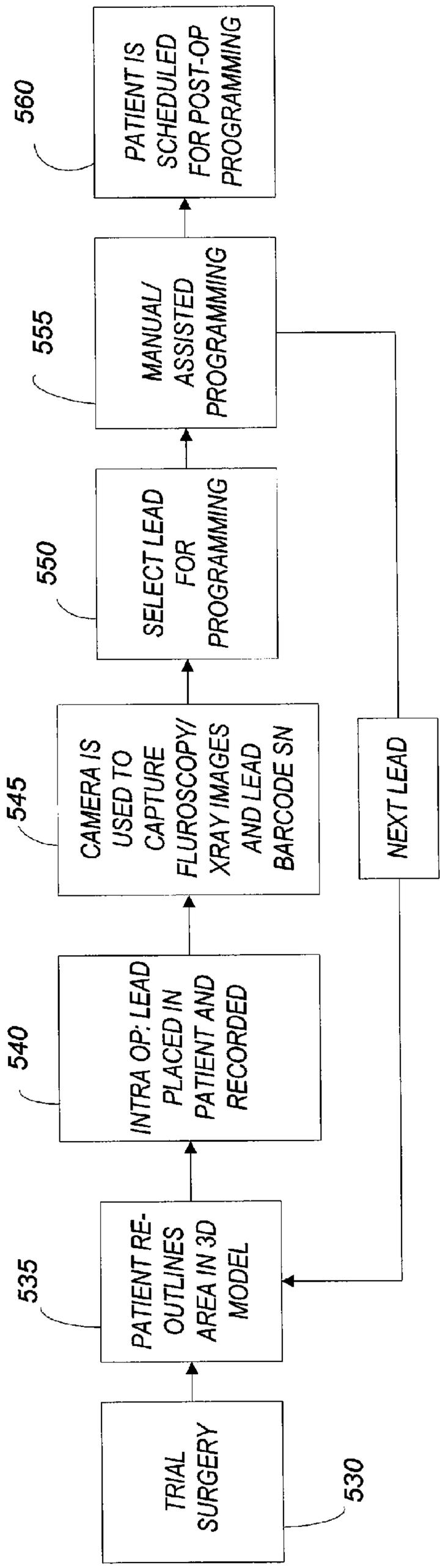

TRIAL SURGERY
530
PATIENT RE-OUTLINES AREA IN 3D MODEL
535
INTRA OP: LEAD PLACED IN PATIENT AND RECORDED
540
CAMERA IS USED TO CAPTURE FLUROSCOPY/ XRAY IMAGES AND LEAD BARCODE SN
545
SELECT LEAD FOR PROGRAMMING
550
MANUAL/ ASSISTED PROGRAMMING
555
PATIENT IS SCHEDULED FOR POST-OP PROGRAMMING
560
NEXT LEAD

FIG. 11

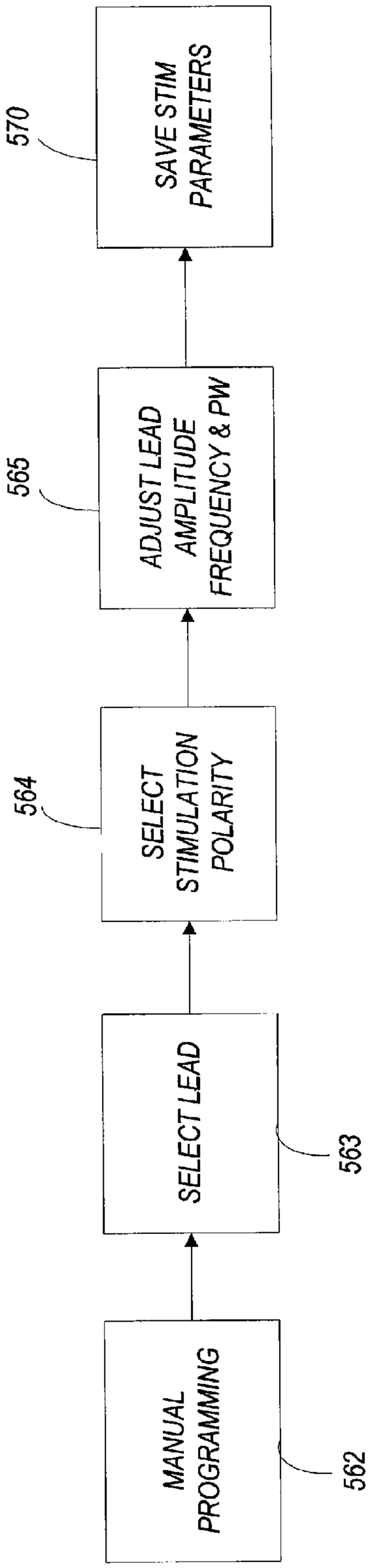

MANUAL PROGRAMMING
562
SELECT LEAD
563
SELECT STIMULATION POLARITY
564
ADJUST LEAD AMPLITUDE & FREQUENCY & PW
565
SAVE STIM PARAMETERS
570

FIG. 12

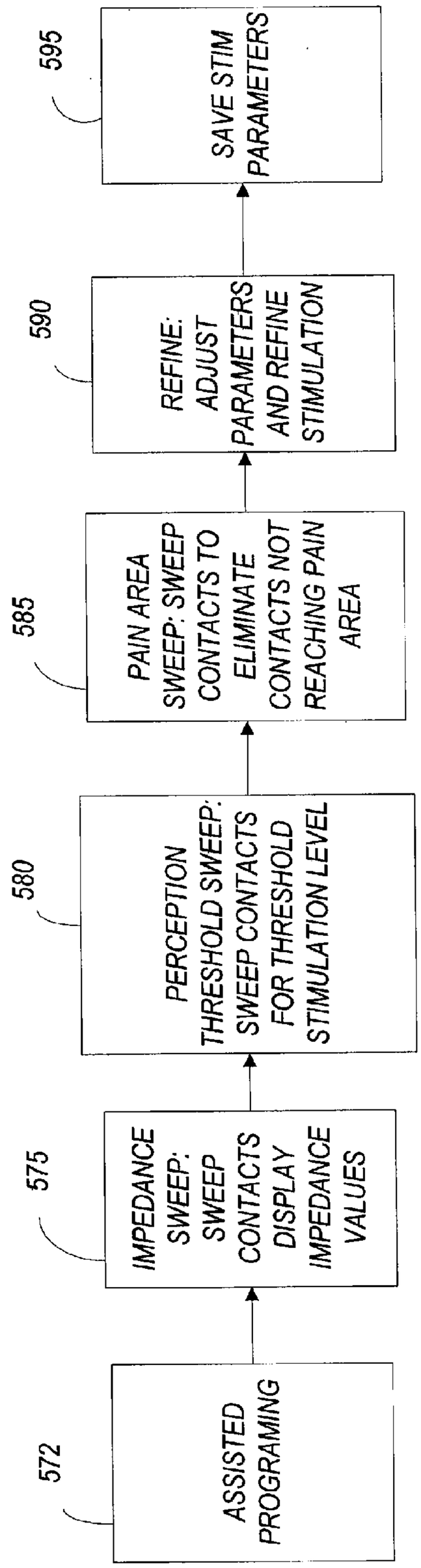

ASSISTED PROGRAMING
572
IMPEDANCE SWEEP: SWEEP CONTACTS DISPLAY IMPEDANCE VALUES
575
PERCEPTION THRESHOLD SWEEP: SWEEP CONTACTS FOR THRESHOLD STIMULATION LEVEL
580
PAIN AREA SWEEP: SWEEP CONTACTS TO ELIMINATE CONTACTS NOT REACHING PAIN AREA
585
REFINE: ADJUST PARAMETERS AND REFINE STIMULATION
590
SAVE STIM PARAMETERS
595

FIG. 13

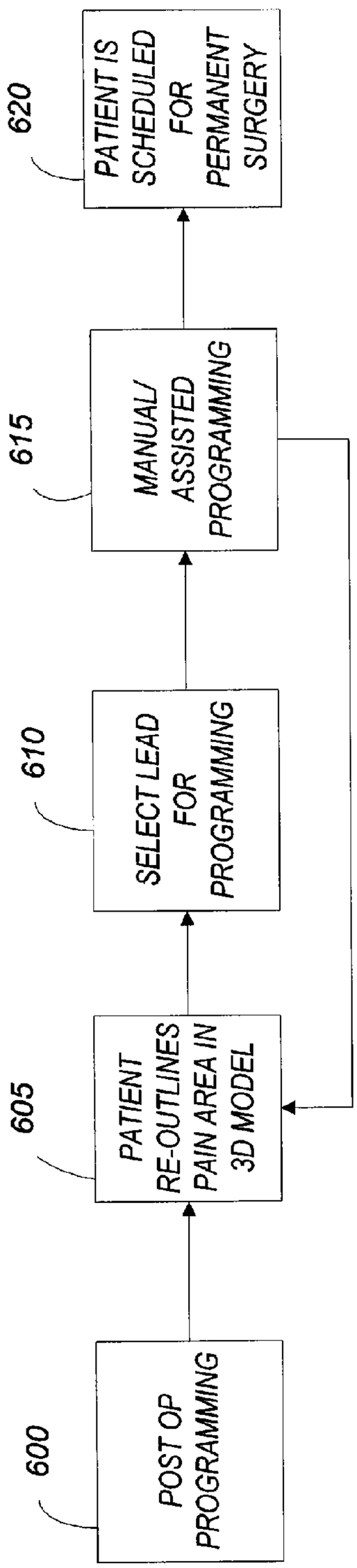

600
POST OP PROGRAMMING
605
PATIENT RE-OUTLINES PAIN AREA IN 3D MODEL
610
SELECT LEAD FOR PROGRAMMING
615
MANUAL/ ASSISTED PROGRAMMING

FIG. 14

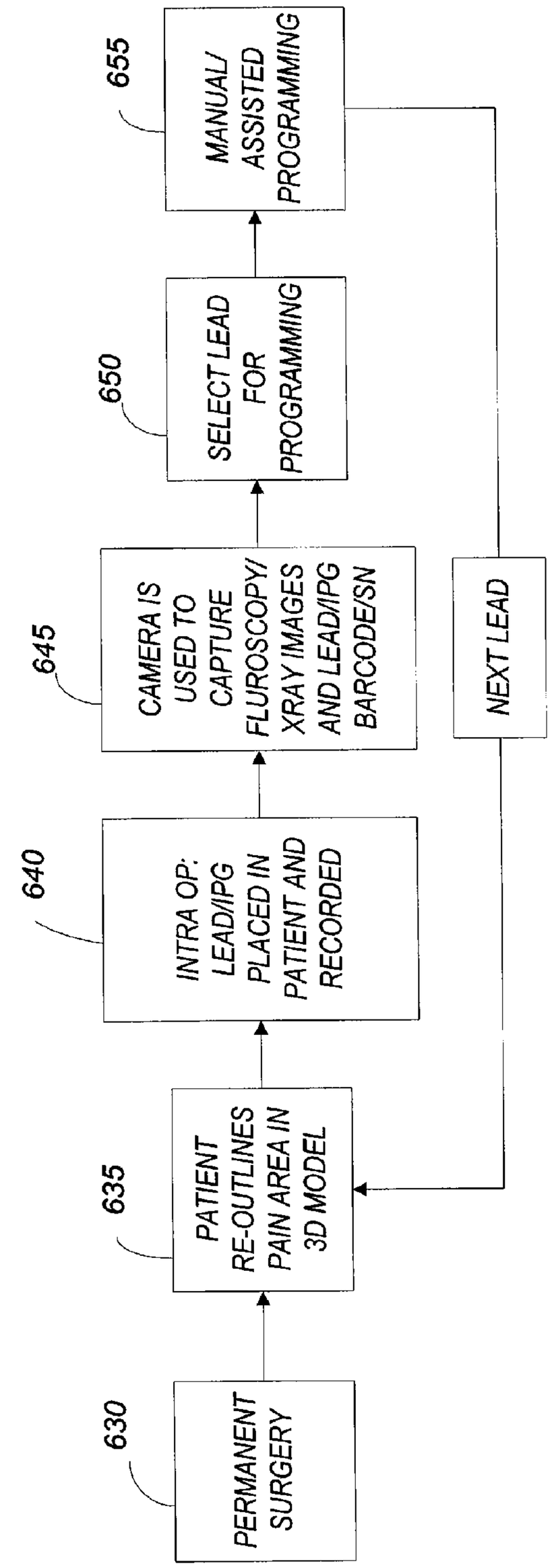

630
PERMANENT SURGERY
635
PATIENT RE-OUTLINES PAIN AREA IN 3D MODEL
640
INTRA OP: LEAD/IPG PLACED IN PATIENT AND RECORDED
645
CAMERA IS USED TO CAPTURE FLUROSCOPY/ XRAY IMAGES AND LEAD/IPG BARCODE/SN
650
SELECT LEAD FOR PROGRAMMING
655
MANUAL/ ASSISTED PROGRAMMING
NEXT LEAD

FIG. 15

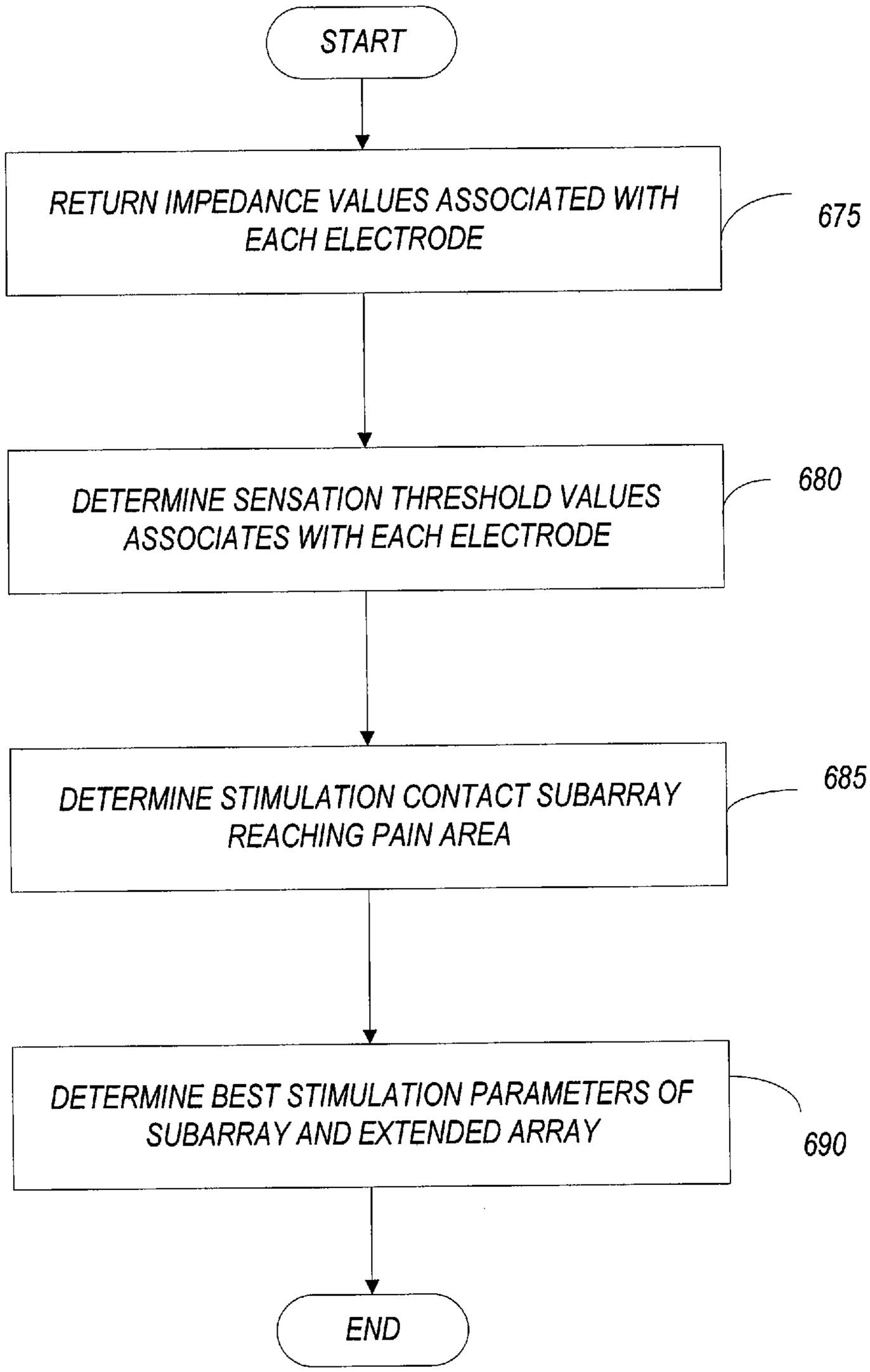

START
RETURN IMPEDANCE VALUES ASSOCIATED WITH EACH ELECTRODE
675
DETERMINE SENSATION THRESHOLD VALUES ASSOCIATES WITH EACH ELECTRODE
680
DETERMINE STIMULATION CONTACT SUBARRAY REACHING PAIN AREA
685
DETERMINE BEST STIMULATION PARAMETERS OF SUBARRAY AND EXTENDED ARRAY
690
END

FIG. 16

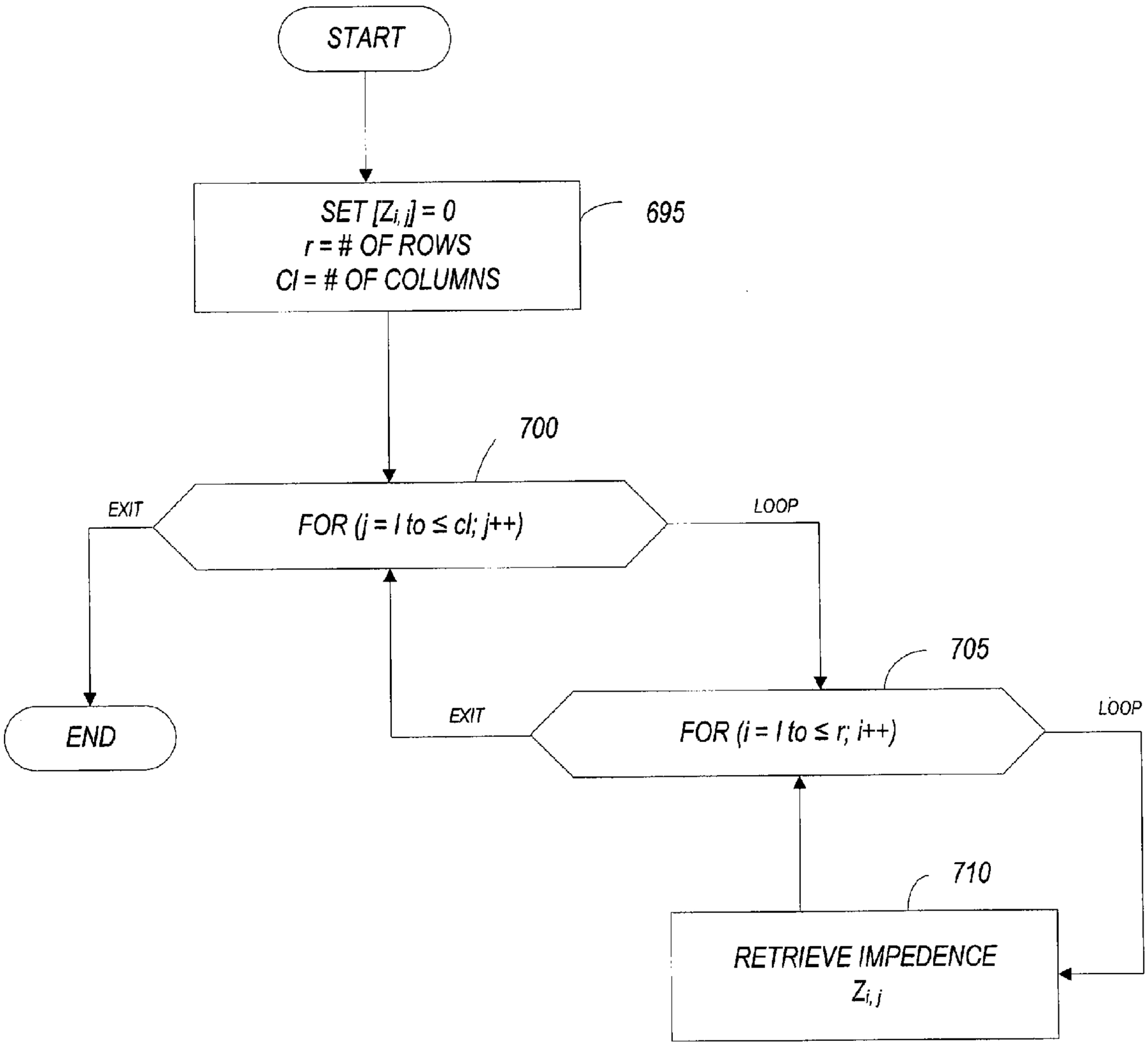

START
SET [Zi, j] = 0
r = # OF ROWS
Cl = # OF COLUMNS
695
700
FOR (j = l to ≤ cl; j++)
EXIT
LOOP
END
705
FOR (i = l to ≤ r; i++)
EXIT
LOOP
710
RETRIEVE IMPEDENCE
Zi, j

FIG. 17

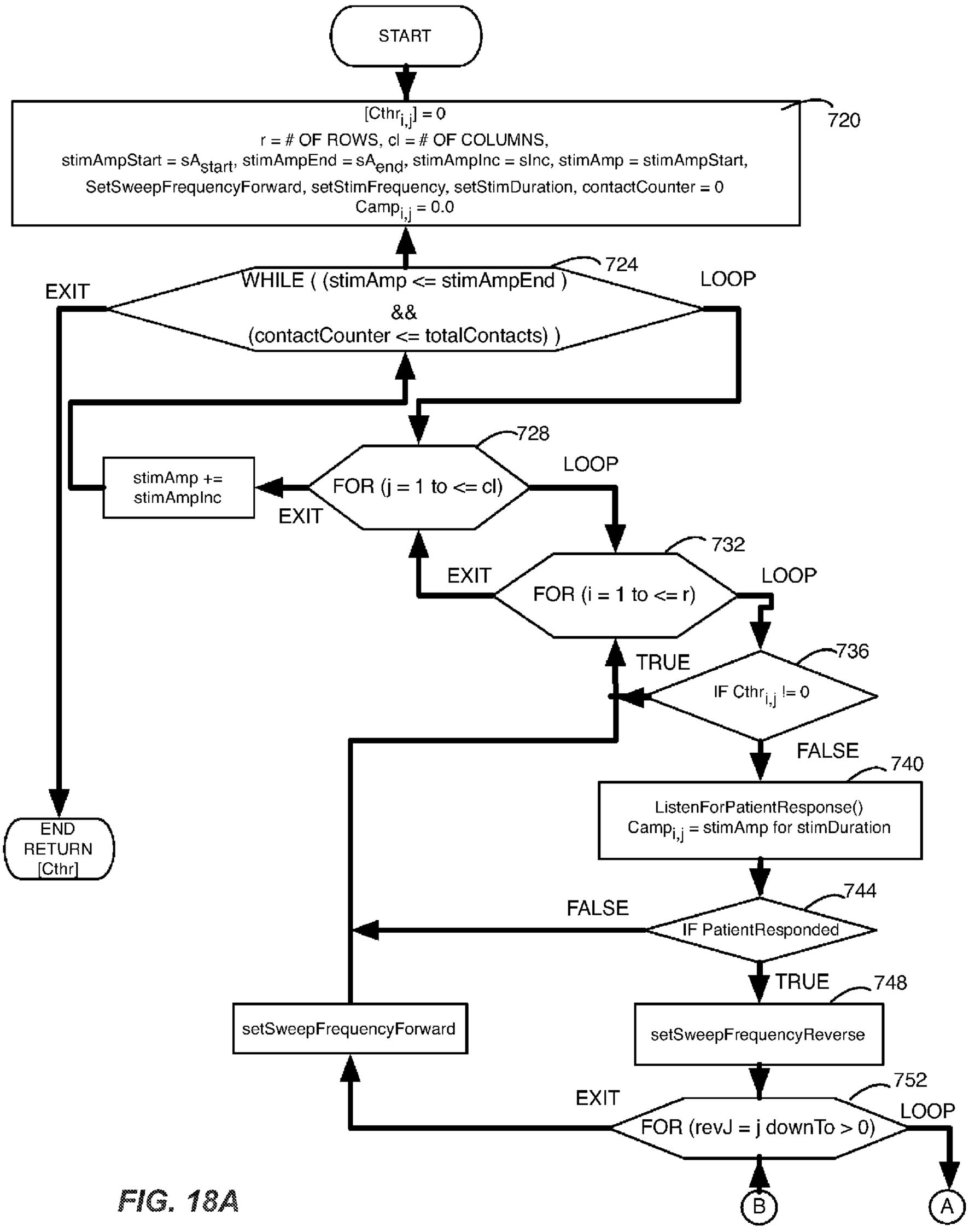

START
[Cthr$_{i,j}$] = 0
r = # OF ROWS, cl = # OF COLUMNS,
stimAmpStart = sA$_{start}$, stimAmpEnd = sA$_{end}$, stimAmpInc = sInc, stimAmp = stimAmpStart,
SetSweepFrequencyForward, setStimFrequency, setStimDuration, contactCounter = 0
Camp$_{i,j}$ = 0.0
720
WHILE ((stimAmp <= stimAmpEnd)
&&
(contactCounter <= totalContacts))
724
EXIT
LOOP
FOR (j = 1 to <= cl)
728
LOOP
EXIT
stimAmp += stimAmpInc
FOR (i = 1 to <= r)
732
EXIT
LOOP
IF Cthr$_{i,j}$!= 0
736
TRUE
FALSE
ListenForPatientResponse()
Camp$_{i,j}$ = stimAmp for stimDuration
740
IF PatientResponded
744
FALSE
TRUE
setSweepFrequencyForward
setSweepFrequencyReverse
748
FOR (revJ = j downTo > 0)
752
EXIT
LOOP
END
RETURN
[Cthr]
B
A

FIG. 18A

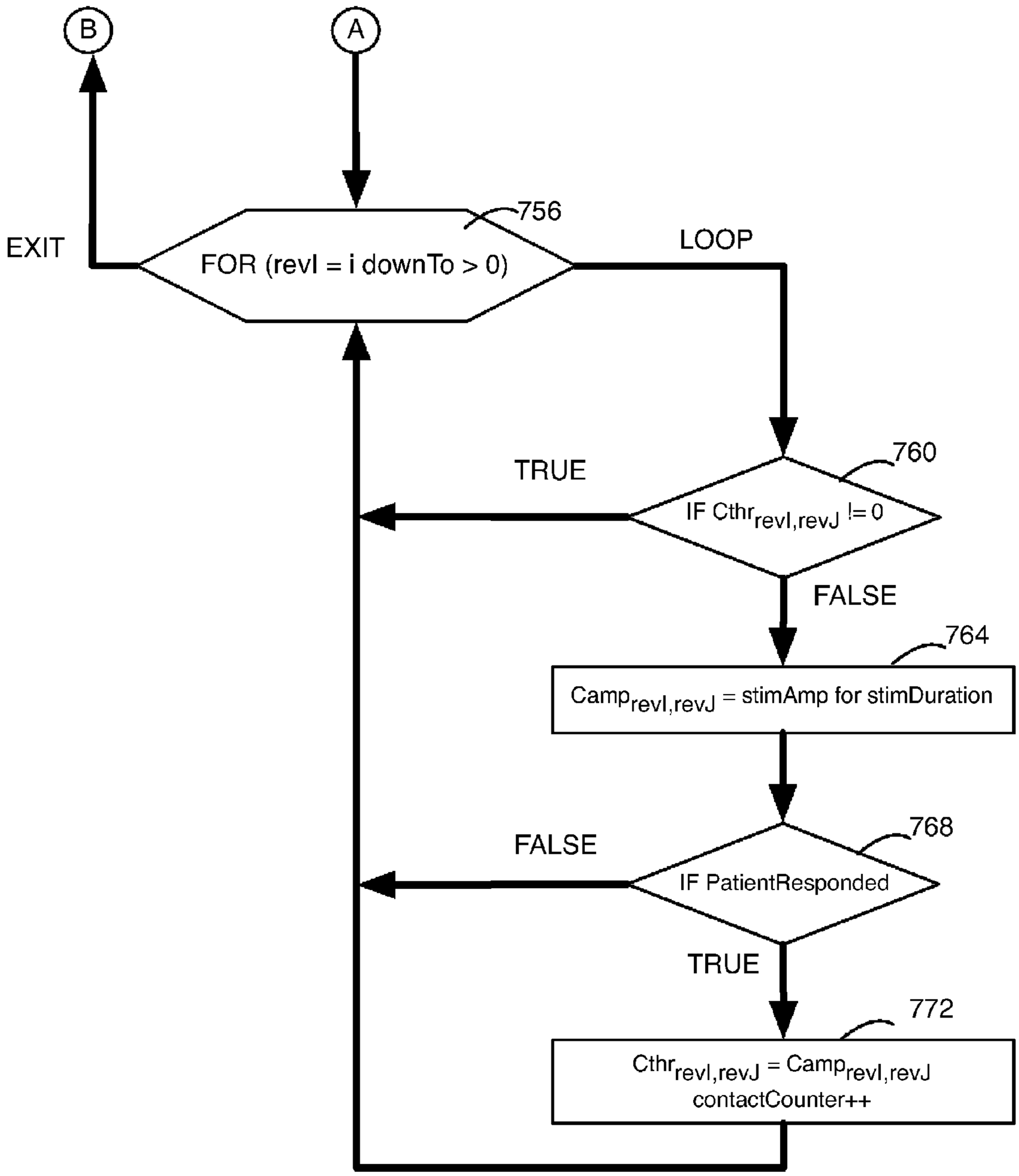

B
A
EXIT
756
FOR (revI = i downTo > 0)
LOOP
TRUE
760
IF Cthr revI,revJ != 0
FALSE
764
Camp revI,revJ = stimAmp for stimDuration
FALSE
768
IF PatientResponded
TRUE
772
Cthr revI,revJ = Camp revI,revJ
contactCounter++

FIG. 18B

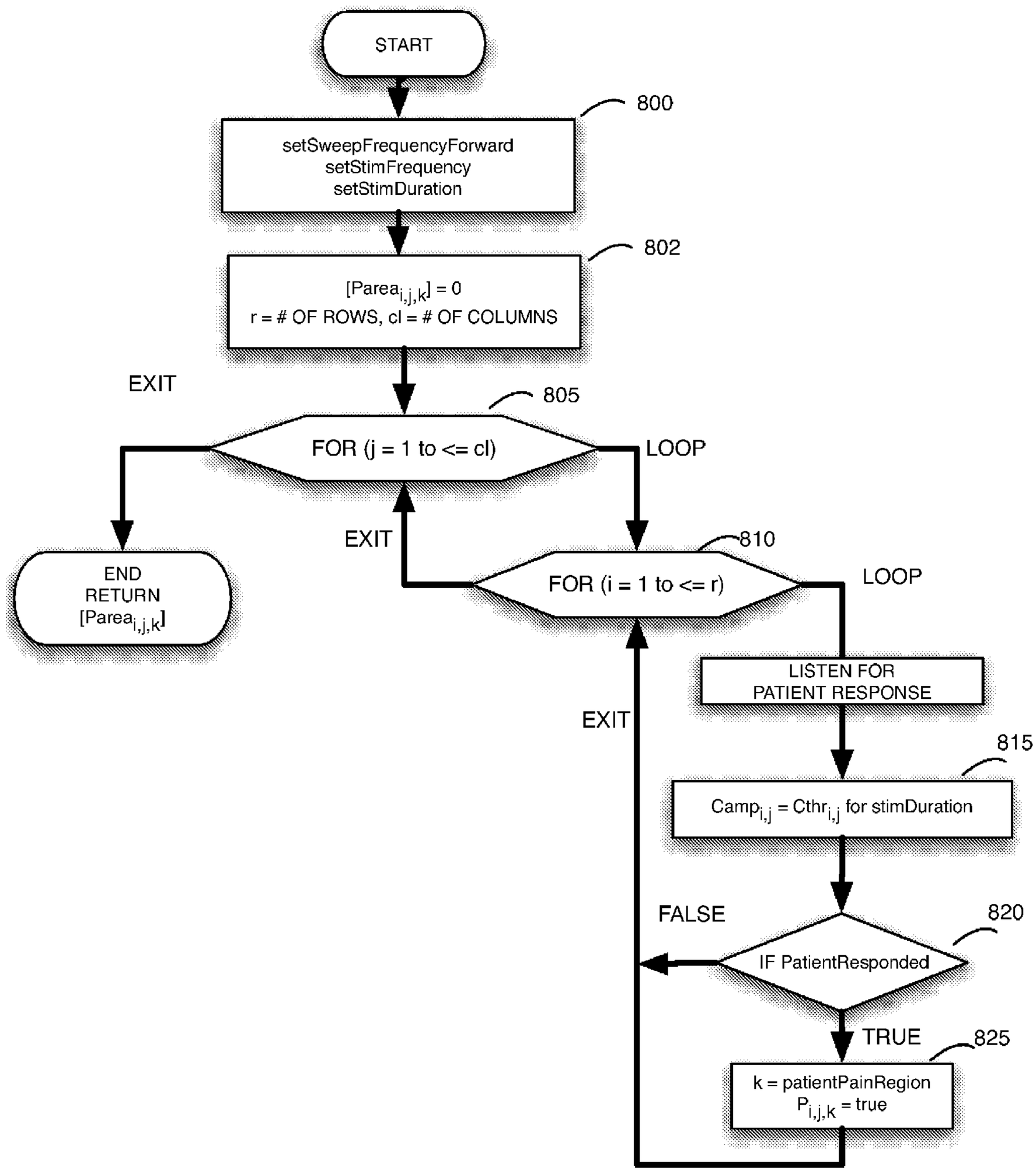

START
800
setSweepFrequencyForward
setStimFrequency
setStimDuration
802
[Parea$_{i,j,k}$] = 0
r = # OF ROWS, cl = # OF COLUMNS
EXIT
805
FOR (j = 1 to <= cl)
LOOP
EXIT
810
END
RETURN
[Parea$_{i,j,k}$]
FOR (i = 1 to <= r)
LOOP
LISTEN FOR
PATIENT RESPONSE
EXIT
815
Camp$_{i,j}$ = Cthr$_{i,j}$ for stimDuration
FALSE
820
IF PatientResponded
TRUE
825
k = patientPainRegion
P$_{i,j,k}$ = true

FIG. 19

SYSTEM AND METHOD OF ESTABLISHING A PROTOCOL FOR PROVIDING ELECTRICAL STIMULATION WITH A STIMULATION SYSTEM TO TREAT A PATIENT

BACKGROUND

The invention relates to a stimulation system, such as a spinal cord stimulation (SCS) system, having a tool for programming an electrical stimulation generator, such as an implantable pulse generator (IPG), of the system. The invention also relates to a method for developing a protocol for the stimulation system.

A spinal cord stimulator is a device used to provide electrical stimulation to the spinal cord or spinal nerve neurons for managing pain. The stimulator includes an implanted or external pulse generator and an implanted medical electrical lead having one or more electrodes at a distal location thereof. The pulse generator provides the stimulation through the electrodes via a body portion and connector of the lead. Spinal cord stimulation programming is defined as the discovery of the stimulation electrodes and parameters that provide the best possible pain relief (or paresthesia) for the patient using one or more implanted leads and its attached IPG. The programming is typically achieved by selecting individual electrodes and adjusting the stimulation parameters, such as the shape of the stimulation waveform, amplitude of current in mA (or amplitude of voltage in V), pulse width in microseconds, frequency in Hz, and anodic or cathodic stimulation.

With newer medical electrical leads having an increased number of electrodes, the electrode and parameter combination increases exponentially. This results in a healthcare professional, such as a clinician, requiring a substantial amount of time for establishing a manually created protocol for providing therapeutic spinal cord stimulation. Therefore, a manual approach for creating a protocol is not an optimal solution for the SCS system.

SUMMARY

Numerous embodiments of the invention provide a method and system for programming an SCS system with a substantially reduced time requirement and increased accuracy. More specifically, in numerous embodiments, a sweep process is used with the electrodes of an implanted medical lead to determine the proper SCS program (also referred to herein as an SCS protocol) for providing the best possible pain relieve for the patient.

In one embodiment, the invention provides a method of establishing a protocol for providing therapeutic electrical stimulation with a stimulation system for treating a patient. The stimulation system includes an electrical stimulation generator; one or more implanted medical leads coupled to the electrical stimulation generator, the one or more implanted medical leads including a plurality of electrodes; a programmer configured to communicate with the electrical stimulation generator; and a patient feedback device configured to communicate with the programmer. The method includes initiating automated and systematic sweeping of the plurality of electrodes with electrical stimuli provided by the electrical stimulation generator in response to communication from the programmer, determining whether the patient provided feedback with the patient feedback device while performing the automated and systematic sweeping, and creating the protocol for providing therapeutic electrical stimulation to treat the patient based on the automated and systematic sweeping of the plurality of electrodes and the patient provided feedback.

In another embodiment, the invention provides a second method of establishing a protocol for providing therapeutic electrical stimulation with a stimulation system for treating a patient. The method includes performing a first automated and systematic sweep through the plurality of electrodes to determine a respective perception threshold associated with each electrode, detecting patient feedback with the patient feedback device while performing the first automated and systematic sweep, and performing a second automated and systematic sweep through the plurality of electrodes to determine an electrode that is associated with a pain area of the patient. The second automated and systematic sweep uses the respective perception thresholds from the first automated and systematic sweep. The second method further includes detecting patient feedback with the patient feedback device while performing the second automated and systematic sweep, and developing the protocol for providing therapeutic electrical stimulation to treat the patient based on the second automated and systematic sweep and the detected patient feedback.

In another embodiment, the invention provides a method of providing therapeutic treatment to a patient with a spinal cord stimulation system. The stimulation system includes a pulse generator, one or more implanted medical leads having a plurality of electrodes coupled to the pulse generator, a programmer in communication with the pulse generator, and a patient feedback device in communication with the programmer. The method includes storing a location of the patient for implanting the one or more leads to receive stimulation, image capturing an aspect of the one or more leads, and establishing a protocol for the one or more leads with the programmer by performing an automated and systematic sweep through the plurality of electrodes.

Other aspects of the invention will become apparent by consideration of the detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial perspective view of a patient using a spinal cord stimulation system.

FIG. **2** is a perspective view of an in-line lead for use in the spinal cord stimulation system of FIG. **1**.

FIG. **3** is a perspective view of a paddle lead for use in the spinal cord stimulation system of FIG. **1**.

FIG. **4** is a block diagram of a patient-feedback device for use in the spinal cord stimulation system of FIG. **1**.

FIG. **5** is a side view of a patient-feedback device inserted in the mouth of a patient

FIG. **6** is a side view of a patient-feedback device with optical sensing.

FIG. **7** is a side view of a patient-feedback device activated by a foot of a patient.

FIG. **8** is a block diagram of an implantable pulse generator for use in the spinal cord stimulation system of FIG. **1**.

FIG. **9** is a block diagram of a clinician programmer for use in the spinal cord stimulation system of FIG. **1**.

FIG. **10** is a flow diagram of a patient performing an initial visit with a clinician.

FIG. **11** is a flow diagram of a patient undergoing an initial visit followed by trial surgery procedure.

FIG. **12** is a flow diagram of the manual programming of a lead.

FIG. **13** is a flow diagram of the computer assisted programming of a lead.

FIG. **14** is a flow diagram of a patient performing a post trial programming session.

FIG. **15** is a flow diagram of a patient undergoing a permanent surgery procedure.

FIG. **16** is a flow diagram of an exemplary computer assisted stimulation programming process for use with the spinal cord stimulation system of FIG. **1**.

FIG. **17** is a flow diagram of an exemplary process for determining impedance values associated with each electrode.

FIGS. **18**A and **18**B are a flow diagram of an exemplary process for determining perception threshold values associated with each electrode.

FIG. **19** is a flow diagram of an exemplary process for determining a stimulation electrode sub-array reaching a pain area of the patient.

DETAILED DESCRIPTION

Before any embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways.

The invention herein relates to an electrical stimulation system for providing stimulation to target tissue of a patient. The system described in detail below is a spinal cord stimulation (SCS) system for providing electrical pulses to the neurons of the spinal cord of a patient. However, many aspects of the invention are not limited to spinal cord stimulation. The electrical stimulation system may provide stimulation to other body portions including a muscle or muscle group, nerves, the brain, etc.

FIG. **1** shows a spinal cord stimulation system **100** in use with a patient **105**. The system includes one or more implanted medical electrical leads **110** connected to an implantable pulse generator (IPG) **115**. The leads **110** include an electrode array **120** at a distal end of the base lead cable. The electrode array **120** includes one or more electrical stimulation electrodes (may also be referred as electrode contacts or simply electrodes) and is placed adjacent to the dura of the spine **125** using an anchor. The spinal column includes the C**1**-C**7** (cervical), T**1**-T**12** (thoracic), L**1**-L**5** (lumbar) and S**1**-S**6** (sacral) vertebrae and the electrode array(s) **120** may be positioned anywhere along the spine **125** to deliver the intended therapeutic effects of spinal cord electrical stimulation in a desired region of the spine. The electrodes (discussed further in FIGS. **2** and **3**) of the electrode arrays **120** promote electrical stimulation to the neurons of the spine based on electrical signals generated by the IPG **115**. In one construction, the electrical signals are regulated current pulses that are rectangular in shape. However, the electrical signals can be other types of signals, including other types of pulses (e.g., regulated voltage pulses), and other shapes of pulses (e.g., trapezoidal, sinusoidal). The stimulation is provided from the IPG **115** to the electrodes via the base lead, which is connected to the IPG **115** with the proximal end of the base lead. The body of the lead can traverse through the body of the patient via the spinal column and from the spinal column through the body of the patient to the implant site of the IPG **115**.

The IPG **115** generates the electrical signals through a multiplicity of electrodes (e.g., four, eight, sixteen, twenty-four electrodes). The IPG **115** can control six aspects of electrical stimulation based on a protocol (may also be referred to as a program): on/off, amplitude (e.g., current or voltage), frequency, pulse width, pulse shape, and polarity (anodic or cathodic stimulation). The stimulation most discussed herein is a regulated (or constant) current that provides a square wave, cathodic stimulation with a variable amplitude, frequency, and/or pulse width. Typically, the IPG **115** is implanted in a surgically made pocket (e.g., in the abdomen) of the patient. However, the pulse generator can also be an external pulse generator (EPG).

The IPG **115** communicates with any one of a clinician programmer (CP) **130**, a patient programmer and charger (PPC) **135**, and a pocket (or fob) programmer (PP) **140**. As discussed in further detail below, the CP **130** interacts with the IPG **115** to develop a protocol for stimulating the patient. The developing of the protocol is assisted with the use of a patient-feedback device (PFD) **145**. Once a protocol is developed, the PPC **135** or the PP **140** can activate, deactivate, or perform limited changes to the programming parameters of the protocol. The protocol may be stored at the IPG **115** or can be communicated and stored at the PPC **135** or the PP **140**. The PPC **135** is also used for charging the IPG **115**.

For the construction described herein, the IPG **115** includes a rechargeable, multichannel, radio-frequency (RF) programmable pulse generator housed in a metallic (e.g., titanium) case or housing. The metallic case is sometimes referred to as the "can" and may act either as a cathode or an anode or floating to the electrical contacts.

Referring now to FIGS. **2** and **3**, the figures show two exemplary leads **110**A and **110**B, respectively, that can be used in the SCS system. A first common type of lead **110** is the "in-line" lead shown in FIG. **2**. An in-line lead **110**A includes individual electrodes **150**A along the length of a flexible cable **155**A. A second common type of lead **110** is the "paddle" lead shown in FIG. **3**. In general, the paddle lead **110**B is shaped with a wide platform **160**B on which a variety of electrode **150**B configurations are situated. For example, the paddle lead **110**B shown in FIG. **3** has two columns of four rectangular shaped electrodes **150**B. A paddle lead typically contains contacts on one side only, but is not restricted to individual electrodes on either side, or electrodes perforating the carrier material.

For both leads shown in FIGS. **2** and **3**, a flexible cable **155**A or **155**B has respective small wires for the electrodes **150**A or **150**B. The wires are embedded within the cable **155**A or **155**B and carry the electrical stimulation from the IPG **115** to the electrodes **150**A or **150**B.

It is envisioned that other types of leads **110** and electrode arrays **120** can be used with the invention. Also, the number of electrodes **150** and how the electrodes **150** are arranged in the electrode array **120** can vary from the examples discussed herein.

The leads shown in FIGS. **2** and **3** are multiple channel leads. Here, a "channel" is defined as a specified electrode **150**, or group of electrodes **150**, that receives a specified pattern or sequence of electrical stimuli. For simplicity, this description will focus on each electrode **150** and the IPG's **115** metallic housing providing a respective channel. When more than one channel is available, each channel may be programmed to provide its own stimulus to its defined electrode.

There are many instances when it is advantageous to have multiple channels for stimulation. For example, different pain locations (e.g., upper extremities, lower extremities) of the patient may require different stimuli. Further, some patients may exhibit conditions better suited to "horizontal" stimula-

tion paths, while other patients may exhibit conditions better suited to "vertical" stimulation paths. Therefore, multiple electrodes positioned to provide multiple channels can cover more tissue/neuron area, and thereby provide better stimulation protocol flexibility to treat the patient.

It is also envisioned that the number of leads **110** can vary. For example, one, two, or four leads **110** can be connected to the IPG **115**. The electrode arrays **120** of the leads **110**, respectively, can be disposed in different vertical locations on the spine **125** with respect to a vertical patient **105**, can be disposed horizontally (or "side-by-side") on the spine **125** with respect to a vertical patient **105**, or some combination thereof.

In alternative to the IPG **115**, the leads **110** can receive electrical stimuli from an external pulse generator (EPG) (also referred to a trial stimulator) through one or more percutaneous lead extensions. An EPG may be used during a trial period.

For the specific construction and operation described herein, a single lead **110** having a two-by-four electrode paddle (as shown in FIG. **3**) is secured to the thoracic portion of the spine **125**. An IPG **115** having a metallic housing is disposed within the patient **105**. The housing acts as another electrode in this contemplated SCS system **100**. Thus, this arrangement results in nine electrodes total. Also, the specifically-discussed system includes nine channels formed by the eight electrodes of the electrode array **120**, respectively, and the metallic housing of the IPG **115**. However, it contemplated that a different number of leads, electrodes, and channels fall within the scope of the invention.

Referring back to FIG. **1**, a user provides feedback to the CP **130** with a PFD **145** while the CP **130** develops the protocol for the IPG **115**. In FIG. **1**, the PFD **145** is an ergonomic handheld device having a sensor (also referred to as input) **165**, a controller, and a communications output **175**. The sensor **165** can take the form of a discrete switch or can take the form of a continuously variable input, such as through the use of a strain gauge. It is envisioned that the use of a continuously variable input can provide magnitude information, thereby providing feedback information.

FIG. **4** provides a block diagram of an exemplary handheld PFD **145** used in the SCS system **100**. The PFD **145** includes two inputs **900** and **905** in communication with the housing of the device **145** and one input **910** internal to the housing. One of the external inputs **900** is a binary ON/OFF switch, preferably activated by the patient's thumb, to allow the patient **105** to immediately deactivate stimulation. The second input **905** includes a force or displacement sensor sensing the pressure or force exerted by the patient's hand. The sensed parameter can be either isotonic (constant force, measuring the distance traversed) or isometric (measuring the force, proportional to pressure applied by patient **105**). The resulting signal from the sensor **905** is analog and, therefore, the signal is conditioned, amplified, and passed to a microcontroller via an analog-to-digital converter.

The internal input **910** for the PFD **145** of FIG. **4** is a motion sensor. The sensor **910**, upon detecting motion, initiates activation of the PFD **145**. The device **145** stays active until movement is not detected by the sensor **910** for a time period. Power is provided by an internal battery **920** that can be replaceable and/or rechargeable.

The processing of the inputs from the sensors **900** and **905** take place in a controller, such as a microcontroller **925**. The microcontroller **925** includes a suitable programmable portion **930** (e.g., a microprocessor or a digital signal processor), a memory **935**, and a bus **940** or other communication lines. Output data of the microcontroller **925** is sent via a Bluetooth bi-direction radio communication portion **945** to the CP **130**. The Bluetooth portion **945** includes a Bluetooth communication interface, an antenna switch, and a related antenna, all of which allows wireless communication following the Bluetooth Special Interest Group standard. Other outputs may include indicators (such as light-emitting diodes) for communicating stimulation activity **950**, sensor activation **955**, and device power **960**, and a speaker and related circuitry **965** for audible communication.

As discussed further below, the patient **105** provides feedback to the SCS system **100**, and specifically the CP **130**, while the CP **130** establishes the protocol for the IPG **115**. The patient **105** can activate the PFD **145** when the patient **105** feels various stimuli, such as paresthesia or pain.

FIGS. **5-7** provide other means for receiving patient feedback. More specifically, FIG. **5** shows a mouth-piece **180** that is inserted into the mouth of the patient. The user provides feedback by biting the mouthpiece. FIG. **6** shows an optical sensor **185** (such as a camera and related image processing software) that detects visual cues from a patient. An example visual cue may be the blinking of the patient's eyes. FIG. **7** shows a foot pedal **190** that receives input by the patient manipulating a switch with his foot. It is also envisioned that the patient may provide feedback directly through the touch screen or hard buttons on the CP **130**.

As discussed earlier, it should be understood that aspects of the SCS system **110** can be applied to other types of electrical stimulation systems. That is, other electrical stimulation systems provide electrical stimuli to other types of target tissues. Similar to the SCS system **110**, these other electrical stimulation systems include one or more medical electrical leads having electrodes, a stimulation generator coupled to the one or more medical electrical leads, and a clinician programmer for establishing a protocol with the stimulation generator.

FIG. **8** shows a block diagram of one construction of the IPG **115**. The IPG **115** includes a printed circuit board ("PCB") that is populated with a plurality of electrical and electronic components that provide power, operational control, and protection to the IPG **115**. With reference to FIG. **8**, the IPG **115** includes a communication portion **200** having a transceiver **205**, a matching network **210**, and antenna **212**. The communication portion **200** receives power from a power ASIC (discussed below), and communicates information to/from the microcontroller **215** and a device (e.g., the CP **130**) external to the IPG **115**. For example, the IPG **115** can provide bi-direction radio communication capabilities, including Medical Implant Communication Service (MICS) bi-direction radio communication following the MICS specification.

The IPG **115**, as previously discussed, provides stimuli to electrodes **150** of an implanted medical electrical lead **110**. As shown in FIG. **8**, N electrodes **150** are connected to the IPG **115**. In addition, the enclosure or housing **220** of the IPG **115** can act as an electrode. The stimuli are provided by a stimulation portion **225** in response to commands from the microcontroller **215**. The stimulation portion **225** includes a stimulation application specific integrated circuit (ASIC) **230** and circuitry including blocking capacitors and an over-voltage protection circuit. As is well known, an ASIC is an integrated circuit customized for a particular use, rather than for general purpose use. ASICs often include processors, memory blocks including ROM, RAM, EEPROM, Flash, etc. The stimulation ASIC **230** can include a processor, memory, and firmware for storing preset pulses and protocols that can be selected via the microcontroller **215**. The providing of the pulses to the electrodes **150** is controlled through the use of a waveform generator and amplitude multiplier of the stimulation ASIC **230**,

and the blocking capacitors and overvoltage protection circuitry of the stimulation portion **225**, as is known in the art. The stimulation portion **225** of the IPG **115** receives power from the power ASIC (discussed below). The stimulation ASIC **230** also provides signals to the microcontroller **215**. More specifically, the stimulation ASIC **230** can provide impedance values for the channels associated with the electrodes **150**, and also communicate calibration information with the microcontroller **215** during calibration of the IPG **115**.

The IPG **115** also includes a power supply portion **240**. The power supply portion includes a rechargeable battery **245**, fuse **250**, power ASIC **255**, recharge coil **260**, rectifier **263** and data modulation circuit **265**. The rechargeable battery **245** provides a power source for the power supply portion **240**. The recharge coil **260** receives a wireless signal from the PPC **135**. The wireless signal includes an energy that is converted and conditioned to a power signal by the rectifier **263**. The power signal is provided to the rechargable battery **245** via the power ASIC **255**. The power ASIC **255** manages the power for the IPG **115**. The power ASIC **255** provides one or more voltages to the other electrical and electronic circuits of the IPG **155**. The data modulation circuit **265** controls the charging process.

The IPG also includes a magnetic sensor **280**. The magnetic sensor **280** provides a "hard" switch upon sensing a magnet for a defined period. The signal from the magnetic sensor **280** can provide an override for the IPG **115** if a fault is occurring with the IPG **115** and is not responding to other controllers.

The IPG **115** is shown in FIG. **8** as having a microcontroller **215**. Generally speaking, the microcontroller **215** is a controller for controlling the IPG **115**. The microcontroller **215** includes a suitable programmable portion **285** (e.g., a microprocessor or a digital signal processor), a memory **290**, and a bus or other communication lines. An exemplary microcontroller capable of being used with the IPG is a model MSP430 ultra-low power, mixed signal processor by Texas Instruments. More specifically, the MSP430 mixed signal processor has internal RAM and flash memories, an internal clock, and peripheral interface capabilities. Further information regarding the MSP 430 mixed signal processor can be found in, for example, the "MSP430G2x32, MSP430G2x02 MIXED SIGNAL MICROCONTROLLER" data sheet; dated December 2010, published by Texas Instruments at its website; the content of the data sheet being incorporated herein by reference.

The IPG **115** includes memory, which can be internal to the control device (such as memory **290**), external to the control device (such as serial memory **295**), or a combination of both. Exemplary memory include a read-only memory ("ROM"), a random access memory ("RAM"), an electrically erasable programmable read-only memory ("EEPROM"), a flash memory, a hard disk, or another suitable magnetic, optical, physical, or electronic memory device. The programmable portion **285** executes software that is capable of being stored in the RAM (e.g., during execution), the ROM (e.g., on a generally permanent basis), or another non-transitory computer readable medium such as another memory or a disc.

Software included in the implementation of the IPG **115** is stored in the memory **290**. The software includes, for example, firmware, one or more applications, program data, one or more program modules, and other executable instructions. The programmable portion **285** is configured to retrieve from memory and execute, among other things, instructions related to the control processes and methods described below for the IPG **115**. For example, the programmable portion **285** is configured to execute instructions retrieved from the memory **290** for sweeping the electrodes **150** in response to a signal from the CP **130**.

The PCB also includes a plurality of additional passive and active components such as resistors, capacitors, inductors, integrated circuits, and amplifiers. These components are arranged and connected to provide a plurality of electrical functions to the PCB including, among other things, filtering, signal conditioning, or voltage regulation, as is commonly known.

FIG. **9** shows a block diagram of one construction of the CP **130**. The CP **130** includes a printed circuit board ("PCB") that is populated with a plurality of electrical and electronic components that provide power, operational control, and protection to the CP **130**. With reference to FIG. **9**, the CP includes a processor **300**. The processor **300** is a controller for controlling the CP **130** and, indirectly, the IPG **115** as discussed further below. In one construction, the processor **300** is an applications processor model i.MX515 available from Freescale Semiconductor. More specifically, the i.MX515 applications processor has internal instruction and data cashes, multimedia capabilities, external memory interfacing, and interfacing flexibility. Further information regarding the i.MX515 applications processor can be found in, for example, the "IMX510EC, Rev. 4" data sheet; dated August 2010; published by Freescale Semiconductor at its website, the content of the data sheet being incorporated herein by reference. Of course, other processing units, such as other microprocessors, microcontrollers, digital signal processors, etc., can be used in place of the processor **300**.

The CP **130** includes memory, which can be internal to the processor **300** (e.g., memory **305**), external to the processor **300** (e.g., memory **310**), or a combination of both. Exemplary memory include a read-only memory ("ROM"), a random access memory ("RAM"), an electrically erasable programmable read-only memory ("EEPROM"), a flash memory, a hard disk, or another suitable magnetic, optical, physical, or electronic memory device. The processor **300** executes software that is capable of being stored in the RAM (e.g., during execution), the ROM (e.g., on a generally permanent basis), or another non-transitory computer readable medium such as another memory or a disc. The CP **130** also includes input/output ("I/O") systems that include routines for transferring information between components within the processor **300** and other components of the CP **130** or external to the CP **130**.

Software included in the implementation of the CP **130** is stored in the memory **305** of the processor **300**, RAM **310**, ROM **315**, or external to the CP **130**. The software includes, for example, firmware, one or more applications, program data, one or more program modules, and other executable instructions. The processor **300** is configured to retrieve from memory and execute, among other things, instructions related to the control processes and methods described below for the CP **130**. For example, the processor **300** is configured to execute instructions retrieved from the memory **140** for establishing a protocol to control the IPG **115**.

One memory shown in FIG. **9** is memory **310**, which can be a double data rate (DDR**2**) synchronous dynamic random access memory (SDRAM) for storing data relating to and captured during the operation of the CP **130**. In addition, a secure digital (SD) multimedia card (MMC) can be coupled to the CP for transferring data from the CP to the memory card via slot **315**. Of course, other types of data storage devices can be used in place of the data storage devices shown in FIG. **9**.

The CP **130** includes multiple bi-directional radio communication capabilities. Specific wireless portions included with the CP **130** are a Medical Implant Communication Service

(MICS) bi-direction radio communication portion **320**, a WiFi bi-direction radio communication portion **325**, and a Bluetooth bi-direction radio communication portion **330**. The MICS portion **320** includes a MICS communication interface, an antenna switch, and a related antenna, all of which allows wireless communication using the MICS specification. The WiFi portion **325** and Bluetooth portion **330** include a WiFi communication interface, a Bluetooth communication interface, an antenna switch, and a related antenna all of which allows wireless communication following the WiFi Alliance standard and Bluetooth Special Interest Group standard. Of course, other wireless local area network (WLAN) standards and wireless personal area networks (WPAN) standards can be used with the CP **130**.

The CP **130** includes three hard buttons: a "home" button **335** for returning the CP to a home screen for the device, a "quick off" button **340** for quickly deactivating stimulation IPG, and a "reset" button **345** for rebooting the CP **130**. The CP **130** also includes an "ON/OFF" switch **350**, which is part of the power generation and management block (discussed below).

The CP **130** includes multiple communication portions for wired communication. Exemplary circuitry and ports for receiving a wired connector include a portion and related port for supporting universal serial bus (USB) connectivity **355**, including a Type-A port and a Micro-B port; a portion and related port for supporting Joint Test Action Group (JTAG) connectivity **360**, and a portion and related port for supporting universal asynchronous receiver/transmitter (UART) connectivity **365**. Of course, other wired communication standards and connectivity can be used with or in place of the types shown in FIG. **9**.

Another device connectable to the CP **130**, and therefore supported by the CP **130**, is an external display. The connection to the external display can be made via a micro High-Definition Multimedia Interface (HDMI) **370**, which provides a compact audio/video interface for transmitting uncompressed digital data to the external display. The use of the HDMI connection **370** allows the CP **130** to transmit video (and audio) communication to an external display. This may be beneficial in situations where others (e.g., the surgeon) may want to view the information being viewed by the healthcare professional. The surgeon typically has no visual access to the CP **130** in the operating room unless an external screen is provided. The HDMI connection **370** allows the surgeon to view information from the CP **130**, thereby allowing greater communication between the clinician and the surgeon. For a specific example, the HDMI connection **370** can broadcast a high definition television signal that allows the surgeon to view the same information that is shown on the LCD (discussed below) of the CP **130**.

The CP **130** includes a touch screen I/O device **375** for providing a user interface with the clinician. The touch screen display **375** can be a liquid crystal display (LCD) having a resistive, capacitive, or similar touch-screen technology. It is envisioned that multitouch capabilities can be used with the touch screen display **375** depending on the type of technology used.

The CP **130** includes a camera **380** allowing the device to take pictures or video. The resulting image files can be used to document a procedure or an aspect of the procedure. For example, the camera **380** can be used to take pictures of barcodes associated with the IPG **115** or the leads **120**, or documenting an aspect of the procedure, such as the positioning of the leads. Similarly, it is envisioned that the CP **130** can communicate with a fluoroscope or similar device to provide further documentation of the procedure. Other devices can be coupled to the CP **130** to provide further information, such as scanners or RFID detection. Similarly, the CP **130** includes an audio portion **385** having an audio codec circuit, audio power amplifier, and related speaker for providing audio communication to the user, such as the clinician or the surgeon.

The CP **130** further includes a power generation and management block **390**. The power block **390** has a power source (e.g., a lithium-ion battery) and a power supply for providing multiple power voltages to the processor, LCD touch screen, and peripherals.

As best shown in FIG. **1**, the CP **130** is a handheld computing tablet with touch screen capabilities. The tablet is a portable personal computer with a touch screen, which is typically the primary input device. However, an external keyboard or mouse can be attached to the CP **130**. The tablet allows for mobile functionality not associated with even typical laptop personal computers.

In operation, the IPG **115** (which may also be an EPG) through the use of the implanted medical electrical leads **110**, and specifically the electrodes **150**, stimulates neurons of the spinal cord **125**. The IPG **115** selects an electrode stimulating configuration, selects a stimulation waveform, regulates the amplitude of the electrical stimulation, controls the width and frequency of electrical pulses, and selects cathodic or anodic stimulation. This is accomplished by a healthcare professional (e.g., a clinician), using the CP **130**, setting the parameters of the IPG **115**. The setting of parameters of the IPG results in a "program," which is also referred to herein as a "protocol," for the electrode stimulation. Programming may result in multiple protocols that the patient can choose from. Multiple protocols allows, for example, the patient to find a best setting for paresthesia at a particular time of treatment.

With reference to FIG. **3**, an electrode array **120** includes eight electrodes **150**B. The shown electrode array **120** has two columns and four rows as viewed along a longitude length of the lead **110**. More generically, the lead includes cl columns and r rows, where cl is two and r is four. When referring to a particular column, the column is referred to herein as the j-th column, and when referring to a particular row, the row is referred to as the i-th row.

Before proceeding further, it should be understood that not all electrode arrays **120** are conveniently shaped as a simple matrix having definite columns and definite rows. More complex configurations are possible, which are referred to herein as complex electrode array configurations. The processes discussed herein can account for complex electrode array configurations. For example, a representative array having cl columns and r rows for a complex electrode array configuration may include "dummy" addresses having "null" values in the array. For a specific example, an electrode contact may span multiple columns. The resulting array may have a first address i, j representing the multiple column electrode and a second address i, j+1 having a "null" value to account for the multiple columns of the multiple column electrode. This concept can be expanded to even more complex arrangements. Accordingly, all electrode arrays **120** can be addressed as a matrix and it will be assumed herein that the electrode array **120** has been addressed as a matrix.

One process of selecting a best protocol for providing electrical stimulation includes four sub-processes. The processes are referred to herein as the impedance sweep of electrodes, the perception-threshold sweep, the pain-coverage sweep, and the parameter fine adjustment. The selecting of a best protocol occurs during a method of treating a patient with spinal cord stimulation. FIGS. **10-15** provide multiple flow diagrams relating to the treatment of the patient **105** using the SCS **100**.

Before proceeding further, it should be understood that the steps discussed in connection with FIGS. **10-15** will be discussed in an iterative manner for descriptive purposes. Various steps described herein with respect to the process of FIGS. **10-15** are capable of being executed in an order that differs from the illustrated serial and iterative manner of discussion. It is also envisioned that not all steps are required as described below.

With reference to FIG. **10**, the patient **105** performs an initial visit (block **500**). The clinician working with the patient **105** logs into the CP **130** (block **505**), and either selects a stored existing patient or adds a new patient to the CP **130** (block **510**). The patient **105** then describes his pain area (block **515**). Using the patient's description, implant sites for a future surgery (block **520**) are determined. The patient **105** is then scheduled for trial surgery (block **525**).

Referring now to FIG. **11**, the patient **105** returns for trial surgery (block **530**). After obtaining the previously stored patient information, the patient **105** again describes his pain area (block **535**) and the location for lead implant sites can be confirmed. During the procedure, one or more leads **110** are placed in the patient **105** and their respective locations recorded in the CP **130** (block **540**). Further, the camera **380** can be used to capture images of the procedure, and capture/read barcode serial numbers of the leads **110** (block **545**). It also envisioned that fluoroscopy/X-ray images can be recorded in the CP **130** as part of the procedure. The result of blocks **540** and **545** is that the CP **130** has a type, location, orientation, and other contextual information relating to the implanting of the lead **110**. This provides a more robust and accurate programming of the lead **110**.

Next (block **550**), the clinician selects the lead **121** for programming. The programming can be manual or assisted (block **555**), both of which are discussed below. The process can then be repeated for a next lead, or the patient is then scheduled for post-op programming (block **560**).

Referring again to block **555**, the clinician either manually or automatically programs the operation of the IPG **115** (which may also be an EPG) to provide electrical stimulation through the lead **110**. With manual programming (FIG. **12**, block **562**), the clinician selects a lead (block **563**), selects a stimulation polarity, which may be cathodal stimulation as it requires the least amount of current (voltage) to elicit a response (block **564**), and manually adjusts pulse amplitude, frequency, and width of the electrical stimuli provided by the electrodes **150** (block **565**). The patient **105** typically provides verbal responses to cues given by the clinician. This in particular is difficult and time consuming during a permanent implant where the patient has to be woken up from the general anesthesia and struggling to be cognitive with often speech impediments. This process can be very time consuming given the number of variables for each electrode/channel. The manual process also does not often result in a "best fit" for providing electrical stimulation treatment and relies significantly on the clinician's experience. The CP **130** saves the resulting protocol of the manually assisted programming (block **570**).

With assisted programming (FIG. **13**, block **572**), the CP **130** establishes a protocol for providing electrical stimuli to the patient **105**. More specifically, the assisted programming first performs three sweeps of the electrodes **150** to result in a best selection of the electrodes **150** for providing paresthesia. The first sweep (block **575**) is an impedance sweep to determine a respective impedance between the IPG **115**, connected lead, each electrode **150**, and tissue. The impedances are displayed on the touch screen **375** and can be used by the clinician to help determine whether an electrode **150** falls in between an accepted impedance range. The second sweep (block **580**) is a perception-threshold sweep to find the minimum threshold stimulation sensed by the patient **105** for each channel/electrode **150**. The second sweep (block **580**) is a perception-threshold sweep to find the minimum threshold. In one implementation, the stimulation sensed by the patient **105** for each channel/electrode **150** is cathodal polarity with the IPG **115** can being the anode. For an EPG, a reference electrode may represent the cathodal anode. The values of the perception-threshold sweep are used to normalize the initial sensation felt by the patient with each electrode **150**. The last sweep (block **585**) is a pain-area sweep to identify the optimal paresthesia electrodes to the pain area. Even more accurately, the pain-area sweep (block **585**) eliminates contacts not reaching the pain area. The clinician can then repeat any of the sweeps and/or refine the paresthesia to the patient (block **590**). The refining of the paresthesia can include adjusting parameters of electric stimulation through the electrodes identified in block **585**, surrounding an electrode identified in block **585** with anode or cathode blocks, or shifting a pattern longitudinally or laterally, as is known in the art. After completion, the CP **130** saves the stimulation parameters (block **595**). Further discussion regarding the CP **130** assisted programming will be provided below.

Before proceeding further, it should be noted that the contextual information relating to the implanting of the lead **110** (from blocks **540** and **545**, above) can be used when programming the stimulation generator. That is, the contextual information can be used to exactly identify the lead **110**, corresponding electrode array **120**, orientation of the lead **110**, the placement of the lead **110**, etc. The CP **130** automatically accounts for this information when establishing the protocol. For a specific example, the CP allows for an anatomically correct placement of the stimulation lead, if the surgeon chooses to orient the lead in another way, such as antegrate or diagonal. The CP **130** accounts for this placement while performing the sweeps.

Referring now to FIG. **14**, the patient **105** returns for post operation programming (block **600**). Again, the patient **105** can describe the pain he is experiencing (block **605**). The clinician then selects a lead **110** for programming (block **610**) and performs manual or assisted programming for the lead **110** (block **615**). The patient is then scheduled for permanent surgery (block **620**).

With permanent surgery (FIG. **15**, block **630**), the operation is similar to the trial surgery except the IPG **115** is typically inserted into the patient. At block **635**, the patient again describes his pain area (block **635**), which typically corresponds to the previously described pain area, and the location for lead implant sites can be confirmed. During the procedure, one or more leads **110** are placed in the patient and recorded in the CP (block **640**). Also, the IPG **115** is placed in the patient and recorded in the CP **130** (block **640**). The camera **380** can be used to capture images of the procedure, capture/read barcode serial numbers of the leads **110**, and capture/read barcode serial numbers of the IPG (block **645**). Further, fluoroscopy/X-ray images can be recorded in the CP **130**, similar to the trial surgery, to help record the procedure (block **645**). Next (block **650**), the clinician selects the lead **110** for programming. The programming can be manual or assisted (block **655**), as already discussed. The process can then be repeated for a next lead **110**.

Accordingly, FIGS. **11-15** provide a process for treating a patient using the SCS **100**. FIGS. **16-19** provide more detailed processes for performing computer assisted stimulation programming (CASP) using the CP **130**. The steps discussed in connection with FIGS. **16-19** will be discussed in an iterative

manner for descriptive purposes. Various steps described herein with respect to the process of FIGS. **16-19** are capable of being executed in an order that differs from the illustrated serial and iterative manner of discussion. It is also envisioned that not all steps are required as described below.

FIG. **16** shows four exemplary sub-processes of the CASP process. The first process (block **675**) retrieves impedance values of the electrodes **150** in a lead **110**. In order to perform the process **675**, the clinician identifies the lead **110** to the CP **130**. The CP **130** knows the arrangement of the electrode array **120**, as previously discussed, for the lead **110** once the lead **110** is identified. One exemplary pseudo code and related flow chart for process **675** is shown below and in FIG. **17**, respectively. This pseudo code assumes impedance between the contact $Z_{i,j}$, connected lead, the can of the IPG **115**, and tissue. However, other impedance combinations are possible between contacts $Z_{i,j}$ and $Z_{k,l}$,
where (k=1:r); (1=1:cl) and (k!=i)∨ (l!=j);

```
Require: EPG or IPG communication established
1: [Z_ij] ← 0                          >setting impedance array to zero
2: r ← number of rows                  >number of contacts in lead latitudinally
3: cl ←number of columns               > number of contacts in lead longitudinally
4: for j = 1 to ≤ cl do
5:     for i = 1 to ≤ r do
6:         Z_ij ← retrieve impedance of contact i, j    >computed by IPG/EPG
7:     end for
8: end for
9: return [Z_ij]
```

First, the array $[Z_{i,j}]$ is set to zero, the number of rows r is identified, and the number of columns cl is identified (block **695**). The array $[Z_{i,j}]$ corresponds to an array representing the electrode array **120**. The letter i represents the i-th row from 1 to r rows. The letter j represents the j-th column from 1 to j columns. As discussed previously, the representative array $[Z_{i,j}]$ can represent many electrode arrays, including complex electrode array configurations having "dummy" addresses with "null" values. Therefore, not every address of the array $[Z_{i,j}]$ may include a value. Returning to FIG. **17**, the process performs a first for-loop (block **700**) for the columns and a second for-loop (block **705**) for the rows of the array $[Z_{i,j}]$. The two loops allow the process to progress through each electrode **150** of the electrode array **120** to obtain an impedance value associated with each channel (block **710**). Each impedance value relates to the impedance between the can **220** of the IPG **115**, the connected lead, tissue, for example, and a respective electrode **150**. The process of FIG. **17** helps to determine that the impedance values of lead **110** fall within acceptable ranges, necessary to provide electrical stimulation to the nerves.

Referring back to FIG. **16**, the second process (block **680**) determines the perception-threshold values of the electrodes **150** in a lead **110**. During the process, the patient **105** provides feedback using the PFD **145** when the patient **105** senses a stimulation, such as a paresthesia sensation. One exemplary pseudo code and related flow chart for process **680** is shown below and in FIG. **18**, respectively.

```
Require: EPG or IPG communication established
Ensure: Impedance of each contact retrieved
1: [Cthr_ij] ← 0                       >setting contact stim threshold array to zero
2: r ← number of rows                  >number of contacts in lead latitudinally
3: cl ←number of columns               >number of contacts in lead longitudinally
```

-continued

```
4: stimAmpStart ← sA_start             >initial stim amplitude
5: stimAmpEnd ← sA_end                 >ending stim amplitude
6: stimAmpInc ← sInc                   >stim amplitude increment
7: stimAmp ← stimAmpStart              >beginning stimulation amplitude
8: setSweepFrequencyForward            >activation frequency
9: setStimFrequency                    >stimulation in pulses per seconds
10 setStimDuration                     >duration of stimulation per contact
11: contactCounter ← 0
12: Camp_ij ← 0
13: while stimAmp ≤ stimAmpEnd && contactCounter ≤ totalContacts do
14:   for j = 1 to cl do
15:     for i = 1 to r do
16:       if Cthr_ij ≠ 0 then          >ignore contacts that already have thresholds established
17:         continue
18:       end if
19:       listenForPatientResponse( )
20:       Camp_ij ← stimAmp for stimDuration >start stimulation
21:       if patientResponded then
22:         setSweepFrequencyReverse, startSweepReverse
23:         for revJ = j downto revJ > 0 do
24:           for revI = i downto revI > 0 do
25:             if Cthr_revI,revJ ≠ 0 then>ignore contacts that already have thresholds established
26:               continue
27:             end if
28:             Camp_revI,revJ ← stimAmp for stimDuration > start stimulation
29:             if patientResponded then
30:               Cthr_revI,revJ ← Camp_revI,revJ
31:               contactCounter ++
32:             endif
33:           end for
34:         end for
35:       end if
36:       setSweepFrequencyForward
37:     end for
38:   end for
39:   stimAmp+ ← stimAmpInc
40: end While
41: return [Cthr_ij]
```

First the array $[Cthr_{i,j}]$ is set to zero, the number of rows r is identified and the number of columns cl is identified (block **720**). Also, the initial stimulation amplitude stimAmpStart, the ending stimulation amplitude stimAmpEnd, and the stimulation amplitude increment stimAmpInc are identified; the variable stimAmp is set; and the counter contactCounter is set. Also, the forward sweep frequency setSweepFrequency-Forward, the stimulation frequency setStimFrequency, the duration of stimulation setStimDuration are established and the stimulation $Camp_{ij}$ is tuned off (block **720**).

The CASP process performs a while-loop to determine the perception-threshold values of the electrodes **150**. The while-loop is performed while the stimAmp value is less than the threshold stimAmpEnd and each contact does not have a perception-threshold value (block **724**). The while-loop includes two for-loops: a first for-loop for the columns of the array (block **728**) and a second for-loop for the rows of the array (block **732**). The two loops allow the CASP process to progress through each electrode **150** of the electrode array **120**. While performing the loops, the process determines whether the perception array does not have a perception value for the i-th row and the j-th column (block **736**). If the array location has a perception-threshold value, then the process returns to block **732**. Otherwise, the process continues.

Before proceeding further, it should be noted that the CASP process automatically and systematically progress through the electrodes **150**. In addition, as shown by block **736**, the CASP process "skips" or passes over an electrode $C_{i,j}$ once a perception threshold $Cthr_{i,j}$ is identified for the elec-

trode **150**. However, the sweeping of the electrodes **150** is still automated and systematic even when this skip process occurs.

Referring now to block **740**, the contact amplitude $Camp_{i,j}$ is set to the stimulation amplitude stimAmp, the process pauses for a duration. At the same time the CASP is monitoring for a patient response. For the implementation discussed herein, the stimulation amplitude is a current amplitude. However, a voltage amplitude or other variable (pulse shape, frequency, width, etc.) can be used and adjusted in place of the current amplitude. If the patient **105** feels a sensation, then they provide feedback to the CP **130** via the PFD **145** (block **744**). If a patient **105** response is detected then the process proceeds to block **748**. Otherwise, the CASP process continues to proceed through the for-loops.

When a patient **105** provides feedback indicating a response, a reverse frequency is set (block **748**) and the sweep is reversed (starting at block **752**). More specifically, for the CASP process discussed herein, the process proceeds quickly through the electrode array **120** and a delayed reaction from the patient **105** is expected. By performing a reverse sweep, the CASP process more accurately confirms a response. The CASP process initiates two for-loops **752-756** in a reverse sweep direction. While performing the reverse sweep, the process "skips" or passes over electrodes **150** having perception thresholds (block **760**). The contact amplitude $Camp_{revI, revJ}$ is set to the stimulation amplitude stimAmp, the process pauses for a duration (block **764**). If a patient **105** feels a sensation, then they provide feedback to the CP **130** with the PFD **145**. If a patient **105** response is detected (**768**), then the process proceeds to block **772**. Otherwise, the CASP process continues to proceed through the for-loops **752** and **756**. At block **772**, the perception-threshold value is set for $Cthr_{revI, revJ}$ and the contactCounter increments.

Upon completion of the perception threshold sweep, perception thresholds $[Cthr_{i,j}]$ are established for each contact **150**. The values of the perception-threshold sweep are used to normalize the initial sensation felt by the patient with each channel/electrode **150**.

Referring again to FIG. **16**, the third process (block **685**) performs a pain-area sweep to determine the best electrode(s) **150** for stimulating neurons to the affected pain area. During this process, the patient **105** again provides feedback using the PFD **145** when the patient **105** senses a defined stimulation. One exemplary pseudo code and related flow chart for process **685** is shown below and in FIG. **19**, respectively.

```
Require: [Cthr_{i,j}] ≠ 0                    >threshold array is not empty
Ensure: stimulation contacts that cover pain
 1:   [Parea_{i,j,k}] ← false
 2:   setSweepFrequencyForward   >activation frequency
 3:   setStimFrequency           >stimulation in pulses per seconds
 4:   setStimDuration            >duration of stimulation per contact
 5:   r ← number of rows              >number of contacts in lead
                                      latitudinally
 6:   cl ← number of columns          >longitudinal columns
 7:     for: j = 1 to ≤ r do
 8:       for i = 1 to ≤ cl do
 9:         listenForPatientResponse( )
10:         Camp_{i,j} ← Cthr_{i,j} for stimDuration >start stimulation
11:         if patientResponse then
12:           k ← patientPpainRegion > patient locates where pain
              region is
13:           PainA_{i,j,k} ← true
14:         end if
15:     end for
16:   end for
17:   return [Parea_{i,j,k}]
```

First, the forward sweep frequency setSweepFrequency-Forward, the stimulation frequency setStimFrequency, the duration of stimulation setStimDuration are established and the stimulation $Camp_{ij}$ is tuned off (block **800**). Next, the number of rows r is identified, the number of columns cl is identified, and the array $[Parea_{i,j,k}]$ is set to false (block **802**). The CASP process then automatically and systematically progresses through the electrodes **150**. A first for-loop (block **805**) for the columns of the area and a second for-loop (block **810**) for the rows of the array are swept. While performing the loops, the electrode $Camp_{i,j}$ is set to the threshold $Cthr_{i,j}$ which may be set from the prior perception-threshold sweep (block **815**). The process pauses for a duration. If the electrode **150** stimulates neurons related to the pain area, then the patient **105** provides feedback to the CP **130** via the PFD **145**. If a patient **105** response is detected (block **820**) then the process proceeds to block **825**. Otherwise, the CASP process continues the automated and systematic sweep through the electrodes **150**. At block **825**, the patient identifies the paresthesia area (k) the stimulation is reaching and contact i,j in the array $[Parea_{i,j,k}]$ is set to true.

In some implementations, when a patient **105** provides feedback indicating a response to the stimulation that reaches the pain area, the sweep can be repeated multiple times over. The resulting multitude pain area arrays can be compared to verify consistent patient response. However, the exemplary process shown in FIG. **19** does not include the repeated sweep.

At the end of the pain-area sweep, the CP **130** identifies the best electrode(s) **150** for stimulating neurons to the affected pain area, i.e., to provide paresthesia to the affected pain areas. It is envisioned that the process of performing the perception threshold sweeps and pain area sweeps can be performed in less than thirty minutes, and preferably in less than ten minutes. The time can vary based on the sweep speed and delay times used during the sweep. The CP **130** can then isolate the resulting best electrodes and refine the stimulation parameters (amplitude, frequency, pulse width) to result in an optimal pattern as has been previously done in prior SCS systems (block **690** of FIG. **16**).

Thus, the invention provides, among other things, useful and systems and methods for providing electrical stimulation to a neural tissue of a patient. Various features and advantages of the invention are set forth in the following claims.

What is claimed is:

1. A method of establishing a protocol for providing therapeutic electrical stimulation with a stimulation system for treating a patient, the stimulation system comprising an electrical stimulation generator, one or more implanted medical leads coupled to the electrical stimulation generator, the one or more implanted medical leads including a plurality of electrodes, a programmer configured to communicate with the electrical stimulation generator, and a patient feedback device configured to communicate with the programmer, the method comprising:

initiating automated and systematic sweeping through the plurality of electrodes with electrical stimuli provided by the electrical stimulation generator in response to communication from the programmer, wherein the initiating step includes

performing a first automated and systematic sweep through the plurality of electrodes to determine a respective perception threshold associated with each electrode, the first automated and systematic sweep including

providing a first electrical stimulus having a first amplitude to a first electrode,

waiting a time period for detecting patient feedback after providing the first electrical stimulus,

then providing a second electrical stimulus having the first amplitude to a second electrode,

waiting the time period for detecting patient feedback after providing the second electrical stimulus,

then providing a third electrical stimulus having the first amplitude to a third electrode,

waiting the time period for detecting patient feedback after providing the third electrical stimulus, and

repeating the providing and waiting steps with the first, second, and third electrical stimuli having a second amplitude greater than the first amplitude, and

performing a second automated and systematic sweep through the plurality of electrodes to determine an electrode that is associated with a pain area of the patient, the second automated and systematic sweep including

providing a fourth electrical stimulus having a third amplitude to the first electrode,

waiting the time period for detecting patient feedback after providing the fourth electrical stimulus,

then providing a fifth electrical stimulus having a fourth amplitude to the second electrode,

waiting the time period for detecting patient feedback after providing the fifth electrical stimulus,

then providing a sixth electrical stimulus having a fifth amplitude to the third electrode,

waiting the time period for detecting patient feedback after providing the sixth electrical stimulus, and

wherein the fourth, fifth, and sixth electrical stimuli are based on the respective perception thresholds from the first automated and systematic sweep;

determining whether the patient provided feedback with the patient feedback device while performing the automated and systematic sweeping, wherein the determining step includes

detecting patient feedback with the patient feedback device while performing the first automated and systematic sweep, and

detecting patient feedback with the patient feedback device while performing the second automated and systematic sweep; and

creating the protocol for providing therapeutic electrical stimulation to treat the patient based on the automated and systematic sweeping through the plurality of electrodes and the patient provided feedback, wherein the creating step includes developing the protocol for providing therapeutic electrical stimulation to treat the patient based on the second automated and systematic sweep and the detected patient feedback.

2. The method of claim **1**, wherein the automated and systematic sweeping includes automatically generating at least one electrical stimulus over a time period corresponding to each electrode in a systematic sequence.

3. The method of claim **2**, wherein the respective electrical stimulus includes a pulse having a constant voltage.

4. The method of claim **2**, wherein the respective electrical stimulus includes a pulse having a constant current.

5. The method of claim **2**, wherein the creating the protocol includes adjusting at least one of amplitude, frequency, pulse width, pulse shape, and stimulation type of an electrical stimulus to refine the protocol.

6. The method of claim **2**, wherein the creating the protocol further includes modifying the enablement or disablement of one of the plurality of electrodes to refine the protocol.

7. The method of claim **1**, wherein the stimulation system includes a spinal cord stimulation system and the stimulation generator includes a pulse generator, and wherein the therapeutic electrical stimulation includes providing paresthesia for the patient.

8. The method of claim **1**, and further comprising performing a third automated and systematic sweep through the plurality of electrodes to determine a respective impedance associated with each electrode.

9. The method of claim **1**, wherein the second automated and systematic sweep includes automatically generating a respective electrical stimulus having a relation to the perception threshold of the electrodes, respectively, for a time period in a systematic sequence.

10. The method of claim **1**, wherein the detecting patient feedback while performing the first automated and systematic sequence results in the method further comprising

pausing the first automated and systematic sweep;

performing a third automated and systematic sweep through the plurality of electrodes in a reverse systematic sequence from the systematic sequence;

detecting patient feedback with the patient feedback device while performing the third automated and systematic sweep; and

reinitiating the first automated and systematic sweep.

11. The method of claim **1**, further comprising:

storing a location of the patient for implanting the one or more leads to receive stimulation; and

image capturing an aspect of the one or more leads.

12. The method of claim **11**, and further comprising image capturing an aspect of the pulse generator.

13. The method of claim **11**, wherein the initiating the automated and systematic sweep includes automatically generating a respective electrical stimulus for a time period with each electrode in a systematic sequence.

14. The method of claim **11**, wherein the initiating the automated and systematic sweep includes performing an automated and systematic sweep through the plurality of electrodes to determine a respective perception threshold associated with each electrode.

15. The method of claim **11**, wherein the initiating the automated and systematic sweep includes performing an automated and systematic sweep through the plurality of electrodes to determine an electrode that is associated with a pain area.

16. The method of claim **11**, wherein the initiating the automated and systematic sweep includes performing a first automated and systematic sweep through the plurality of electrodes to determine a respective perception threshold associated with each electrode, and performing a second automated and systematic sweep through the plurality of electrodes to determine an electrode that is associated with a pain area.

17. A method of establishing a protocol for providing therapeutic electrical stimulation with a stimulation system for treating a patient, the stimulation system comprising an electrical stimulation generator, one or more implanted medical leads coupled to the electrical stimulation generator, the one or more implanted medical leads including a plurality of electrodes, a programmer configured to communicate with the electrical stimulation generator, and a patient feedback device configured to communicate with the programmer, the method comprising:

initiating automated and systematic sweeping through the plurality of electrodes with electrical stimuli provided by the electrical stimulation generator in response to communication from the programmer, wherein the auto-

mated and systematic sweeping includes automatically generating at least one electrical stimulus over a time period corresponding to each electrode in a systematic sequence, including

providing a first electrical stimulus with a first amplitude to a first electrode,

then providing a second electrical stimulus with the first amplitude to a second electrode, and

then providing a third electrical stimulus with the first amplitude to a third electrode;

determining whether the patient provided feedback with the patient feedback device while performing the automated and systematic sweeping, wherein the determining step includes receiving a feedback signal from the feedback device;

pausing the automatically generating the at least one electrical stimulus in the systematic sequence;

automatically generating a second at least one electrical stimulus over a second time period with the plurality of electrodes in a reverse systematic sequence from the systematic sequence, including

providing the second electrical stimulus with the first amplitude to the second electrode,

then providing the first electrical stimulus with the first amplitude to the first electrode;

determining whether the patient provided feedback with the patient feedback device while automatically generating the second at least one electrical stimulus; and

creating the protocol for providing therapeutic electrical stimulation to treat the patient based on the automated and systematic sweeping through the plurality of electrodes, and the patient provided feedback.

18. The method of claim **17**, wherein the initiating the automated and systematic sweeping includes performing an automated and systematic sweep through the plurality of electrodes to determine a respective perception threshold associated with each electrode.

19. The method of claim **17**, wherein the initiating the automated and systematic sweeping includes performing an automated and systematic sweep through the plurality of electrodes to determine an electrode that is associated with a pain area.

20. The method of claim **17**, wherein the initiating the automated and systematic sweeping includes performing a first automated and systematic sweep through the plurality of electrodes to determine a respective perception threshold associated with each electrode, and performing a second automated and systematic sweep through the plurality of electrodes to determine an electrode that is associated with a pain area.

21. The method of claim **20**, wherein the first automated and systematic sweep and the second automated and systematic sweeps are performed in less than thirty minutes.

* * * * *